Draft Options for the Regulation of Prescribing and Dispensing in New Zealand

Submission to the Ministry of Health

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About the New Zealand Nurses Organisation

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand. NZNO represents over 47,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment related matters. NZNO is affiliated to the International Council of Nurses and the New Zealand Council of Trade Unions.

NZNO promotes and advocates for professional excellence in nursing by providing leadership, research and education to inspire and progress the profession of nursing. NZNO represents members on employment and industrial matters and negotiates collective employment agreements.

NZNO embraces te Tiriti o Waitangi and contributes to the improvement of the health status and outcomes of all peoples of Aotearoa New Zealand through influencing health, employment and social policy development enabling quality nursing care provision. NZNO's vision is *Freed to care, Proud to nurse*.

EXECUTIVE SUMMARY

1. The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on Draft Options for the Regulation of Prescribing and Dispensing in New Zealand.

2. NZNO has consulted its members and staff in the preparation of this submission, including members of our Colleges, Sections, regional councils, Board, Te Rūnanga o Aotearoa and professional nursing, policy, legal, and research advisers. We have also consulted broadly within the nursing sector.

3. NZNO strongly supports replacing the obsolete Medicines Act 1981 and Medicines Regulations 1984 with a comprehensive regime to enable New Zealanders' safe, timely, equitable and efficient access to medicines, medical devices and cell and tissue therapies (and hybrids thereof) as needed.

4. NZNO recognises the Health Practitioners Competence Assurance Act 2003 (HPCAA) as a robust foundation for such a regime, ensuring a high quality regulated workforce that is responsive to changes in health demand, new technologies, and models of care.

5. Some progress towards a more integrated approach to medicines has been made with authorised prescribing by non-medical clinicians and, more recently, legislative changes foreshadowed by the Health Practitioners (Replacement of Statutory References to Medical Practitioners) Bill.

6. The thrust of the proposals for prescribing and dispensing outlined in this document are a further and significant step forward. We warmly welcome the approach of having broad, high-level legislation, underpinned by robust processes for detailing practitioner responsibilities and practice, in line with knowledge and practice.

7. This is consistent with NZNO's long-held view that the exclusive statutory term for registered health practitioners should be "health practitioner", defined as "Health practitioner has the same meaning as in section 5 of the HPCA Act 2003".

8. While the document is clear that the proposed intent is not to name prescriber groups in the governing statute, the differences between the two options for pathways authorising who can prescribe were not as obvious and this has possibly limited discussion and feedback on each option.

9. Our understanding is that option one proposes that the power to authorise classes of prescribers would be determined by regulations i.e. authorisation would sit at Ministerial level, while option two proposes that the responsible authorities (RA) would determine which class of the practitioners for whom it is responsible would be able to prescribe. NZNO supports option two.

10. Responses to the consultation questions on Part B follow some brief comments on Part A below. In summary, NZNO:

    - **supports** in principle the proposed changes to regulation of therapeutic products;

    - **supports** the authority and current practice of Responsible Authorities (RAs) under the HPCAA, in determining health practitioners' scopes of practice, including prescribing and dispensing activities;

    - **notes** that professional bodies have the experience knowledge, and expertise to guide/advise therapeutics classification and best practice and must be empowered to contribute to regulatory processes;

    - **recommends** you consider the risks of inappropriate 'prescribing' and 'dispensing' in the rapidly expanding non-regulated health workforce, for which there is currently no control, and regulate accordingly;

    - **recommends** that the strategic objectives should encompass more fully the concepts of consumer protection and equity;

    - **recommends** that direct to consumer advertising of prescription medicines be banned;

- **notes** that delegated prescribing is not relevant for the nursing workforce;

- **recommends** mandated Māori and consumer representation on relevant regulatory bodies; and

- **recommends** the new regime for therapeutic products is aligned to both health objectives and health workforce education and employment.

11. We have attached NZNO's Practice guideline: Position Statement on Standing Orders which we recommend to your attention. It is also available online[1].

PART A

12. The current regulatory context is accurately, if briefly, described in Part A of the document. However, we suggest there are two significant factors which have not been considered and warrant consideration in the upcoming therapeutics legislation.

13. The first concerns the rapid expansion of the **non-regulated health workforce**. Unregulated health workers work in many health settings, including acute wards in tertiary institutions, and with patients with complex health needs, in both clinical and residential situations. Their job descriptions often include clinical interventions such as administering medications, the use of medical devices, dressings etc.

14. It is clear that there is potential for inadvertent and/or inappropriate 'prescribing and dispensing' activity by non-regulated workers and indeed this is currently happening in some services, eg aged care, disability, mental health and social support services, where the bulk of hands-on care and support is delivered by unregulated workers, often under limited or off-site clinical supervision.

15. While there are strong disciplinary mechanisms under the HPCAA to ensure that regulated practitioners work within their scope of practice, and protect patient safety, there is no equivalent for the non-regulated workforce.

16. As NZNO pointed out in its 2007 submission on the HPCAA Review, cheaper, unregulated workers who are not restricted to working within a scope of practice have presented an attractive alternative to some employers; however the *ad hoc* transition from a trained nursing workforce to one with a large component of unregulated workers without robust workforce planning, training and regulation, has also presented a significant risk to public safety and workforce

[1] http://www.nzno.org.nz/Portals/0/publications/Standing%20Orders%20,%202015.pdf

sustainability. (We also note Physicians assistants are in this category and are likely to be afforded delegated prescribing rights. Robust measures must be in place to ensure that prescribing by such groups is safe and that such unregulated groups are covered off by a relevant Regulatory Authority in regard to responsibility for prescribing.)

17. The Kaiāwhina Action Plan, a joint Ministry of Health /Careerforce initiative to develop nationally consistent training and qualifications for non-regulated health, community and social care workers (under the umbrella title Kaiāwhina), along with other employment and policy indicators, signals the intention to further develop and substantially grow this workforce. It would be a counterproductive, and unsafe, to develop new therapeutics regulations which did not clarify restrictions and responsibilities and accountabilities for kaiāwhina.

18. Regulations must encompass the non-regulated workforce. NZNO suggests, for example, that non-regulated health workers caught prescribing and dispensing, and employers who fail to provide adequate training or direction with regard to such activities, should be liable to prosecution. Though this is ostensibly covered by prescribing and dispensing being "regulated activities", the parameters are not well understood by non-clinicians, educators and providers and this is an area where regulation is needed to sharpen boundaries that are increasingly blurred.

19. Secondly, we suggest the regulations need to be strengthened in relation to **consumer protection** and **equity.** Therapeutics are indeed not "ordinary items of commerce". Consumers need to be protected not only against unsafe products, prescribing and dispensing, but also against advertising, information, and contexts which do not support the use of therapeutic products for improved population health outcomes.

20. "Patient choice" is a strong focus of this government's "Better, Sooner, More Convenient" health strategies, yet here (Table, p7), as elsewhere, the factors influencing "choice" are neither acknowledged nor addressed. Health literacy i.e. the level of understanding people have about health, influences people's lifestyle choices, motivation, treatment compliance and outcomes, while access to affordable assessment, medicines etc. affects their ability to act on their choices.

21. Lack of equitable access to affordable medicines contributes to unnecessary suffering, health disparities and the high cost of treating preventable illness. There are numerous studies indicating that Māori, for example, who have high rates of many chronic diseases, do not access appropriate funded medicines. Equally it is clear that there is concern about 'overmedication' in some circumstances, and that health choices are influenced by the environment, including advertising, availability of products, social media etc.

22. The ability to purchase medications directly on-line is a new potential threat to individual and public safety as they can be obtained without appropriate assessment, and may be dangerous or improperly used. For example, the misuse of antibiotics could contribute to increased antibiotic resistance.

23. It is essential that regulations support a responsible attitude to medicines by prohibiting direct to consumer advertising of prescription and controlling online purchasing. Regulations should also address structural discrimination by *prioritising* and facilitating equitable access to therapeutic products.

24. Regulations must assure robust Māori and consumer representation and consultation at all levels.

Prescribing

25. We suggest that the act of prescribing should be described as "part of an *ongoing* process which starts with assessment" since a significant issue with medications is restricted opportunities for reassessment and safe transition to new, or no, medications.

Dispensing

26. With regard to dispensing we note that nurses are able to "issue" medicines under standing orders and that in some situations the distinction is a barrier to timely access to medications eg when there is no access, or a financial barrier, to an afterhours pharmacy or a GP. Similarly, day surgery, increasingly used to meet elective surgery targets, often requires a package of care which includes medications dressings, referral to a District Nurse etc. As medications must be specifically dispensed and individually labelled, there can be a conflict for the nurse between meeting both the individual needs of the patient meeting and the dispensing guideline.

27. In some services, such as family planning, nurses are engaged in a form of dispensing using medication obtained by practitioner supply order.

28. The new regulatory regime must enable providers to meet people's need for therapeutic products in the above circumstances, for example by enabling them to authorise or credential health practitioners to dispense under certain circumstances.

Categories of prescriber

29. The table (p4) lists a limited number of designated prescribers, but wording should accommodate the inevitable growth of this category eg "and future practitioner groups as approved'.

30. NZNO does not support a delegated prescriber category for nurses.

Other regulatory mechanisms

31. NZNO supports the review of the Misuse of Drugs Act 1975 and Regulations 1977.

Interface with subsidised medicines

32. NZNO supports the continuation of subsidised medicines being set out in the New Zealand Pharmaceutical Schedule rather than in legislation.

33. However, we suggest PHARMAC may have to review the way it restricts access to funded medicines under a more enabling regime. It would be inconsistent to continue to use Special Authority forms to limit access to medicines based on the discipline of the prescriber, (eg whether they are GPs or nurses, or pharmacists) rather than the competence of the practitioner.

34. NZNO again expresses its concern about the potential impact of the Trans Pacific Partnership Agreement (TPPA) which may adversely affect the cost of procuring and utilising pharmaceuticals and medical devices. To date, there has been no independent analysis of the public health implications of the final TPPA provisions for Aotearoa New Zealand, an inevitable situation given the lack of access to relevant information and opportunity for public scrutiny.

35. NZNO was one of the applicants in recent judicial review of an Official Information Act request which found that information about the TPPA was unlawfully kept confidential (Kelsey v the Minister of Trade [2-15] NZHC 2497 [13 October 2015].

36. We would welcome a regulatory regime for therapeutic products that had a mechanism, or that embedded processes, assuring transparency and robust protection of public health interests.

PART B: OPTIONS FOR DISCUSSION

AUTHORISED AND DESIGNATED PRESCRIBERS

- Are there other issues with the current regulatory arrangements that establish authorised and designated prescribers?
- Do you have any comments concerning the principles that govern the authorisation of prescribing in paragraph 44?
- Given the example outline above, are there further details needed in a scope of practice to authorise prescribing or to authorise the ability to issue a Standing Order?

37. We agree that the issues outlined in clause 41 are the main regulatory barriers to establishing authorised and designated prescribers to

ensure timely, equitable access to therapeutics products and efficient workforce utilisation.

38. However, there are other factors that impact the development and approval of new prescriber classes. Regulatory bodies necessarily rely heavily on input from practising clinicians, and their respective professional bodies and specialist colleges; this essential advisory role and the development of current practice guidelines and standards requires considerable voluntary commitment and motivation from expert practitioners.

39. The National Diabetes Nursing Knowledge and Skills Framework (NDNKSF), developed by NZNO's Diabetes Nurse Specialists, the College of Nurses Aotearoa and diabetes specialists, for example, provided the enabling platform for diabetes nurse prescribers (designated prescribers) in 2011.

40. It will be important to consider how regulations can facilitate the development of robust standards and accreditation programmes for prescribing in non-medical professions, where it is well established, without placing undue pressure or unrealistic expectations on the voluntary advisory capacity of expert practitioner organisations, or imposing significant costs and unlimited power on RAs. Ie Resourcing issues should be considered.

41. Interdisciplinary understanding of scopes of practice is, in NZNO's experience, relatively limited.

42. This has delayed both uptake and recognition of new and expanded scopes of practice and, without further education and consultation, may continue to obstruct the extension of prescribing rights across the regulated health workforce and further delay more timely and equitable access to prescription medicines.

43. For nurses, further delays to the two prescribing levels (specialist and community nurse prescribing) currently being developed, *and/or* lack of education/employment opportunities to develop and utilise new skills would have a significant and adverse impact on the profession and nursing leadership. Moreover, it would severely limit the capacity of the health workforce to manage New Zealanders' health needs equitably and affordably.

44. A holistic, planned approach is necessary to ensure the new regulatory regime for therapeutic products is aligned to health objectives and health workforce education and employment.

45. Diabetes nurse prescribing has proved to be safe and effective[2] but the way it was introduced via Health Workforce New Zealand's precipitate pilot programme[3], the relatively limited uptake (there are currently 23 diabetes nurse prescribers), and the failure to extend this expanded practice model to other areas of high health need - eg respiratory nurse prescribing – indicates what we anticipated: that it is time-consuming and duplicative to remove prescribing barriers one group at a time.

46. This underlines the need for the regulatory regime to be as transparent and straightforward as possible to avoid the risk of having to replicate the same cumbersome process for every area of health within a scope of practice where innovative practice could make a significant difference to population health.

47. Of the regulatory changes proposed, the first option simply shifts the authorising of classes of practitioner entitled to prescribe from the primary legation to the subordinate legislation – the regulations – so that change can be more easily and rapidly made when required by amendment of the regulation rather than the need to amend a statute.

48. This would be an improvement on the current process, but would not offer the same consistency and flexibility as the second proposal which would shift the authorisation of particular classes of practitioner to prescribe from Parliament (under the primary legislation) to the RA under the HPCAA.

49. Under this proposal, changes in authorisation e.g. the addition of a particular class of practitioner as authorised to prescribe – would be made by the RA by changing the scope of practice and gazetting the change.

50. NZNO prefers the latter approach as it is concordant with the HPCAA which gives RAs responsibility and control over scopes of practice under their respective jurisdictions; prescribing and dispensing are activities undertaken by practitioners and part of their scopes of practice.

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[2] Jill Wilkinson, Jenny Carryer, Jeffery Adams, & Sandy Chaning-Pearce, Evaluation of the Diabetes Nurse Specialist Prescribing Project, October 2011, retrieved January 2016 http://www.nzssd.org.nz/documents/dnss/DNS%20prescribing%20%20project%20final%20report%202011.pdf

[3] See NZNO's submission to Health Workforce Innovations Team, Ministry of Health, and Nursing Council of New Zealand (September 2010) on the Nurse Prescribing in Diabetes Services Consultation http://www.nzno.org.nz/get_involved/submissions/articletype/archiveview/year/2010

51. This option would effectively remove several regulatory and bureaucratic barriers currently obstructing the purpose and operation of the HPCAA i.e. to assure a high quality regulated workforce that can respond safely, quickly and efficiently to changes in health demand, new technologies, and models of care.

52. NZNO supports the principles governing the authorisation of prescribing listed in clause 44 i.e. that authorised prescribers:

    - must be regulated practitioners under the HPCAA;
    - must prescribe within his/her scope of practice specified by the RAs; and that
    - RAs have statutory accountability for establishing scopes of practice, prescribing qualifications for registration within that scope, and assuring the ongoing fitness and competence of registered practitioners.

53. We are confident that the HPCAA and RAs are sufficient to manage the scopes and requirements for prescribing and dispensing.

54. With regard to **designated prescribing**, we draw your attention to a technical difference between prescribing as part of advanced practice in a specialty area, as with a Diabetes Nurse Prescriber (DNP) for example, and prescribing as part of a scope of practice. Technically, DNP is not a defined nursing scope of practice (the nursing scopes of practice are Registered Nurse, Enrolled Nurse and Nurse Practitioner) – though, of course, it is within the scope of nursing practice.

55. Prescribing (within set limitations) within the nursing scope of practice set by the RA would enable nurses to prescribe within the area of practice eg school nurses would be able to prescribe treatment for lice, family planning nurses would be able to prescribe ECP, etc. This would certainly give effect to the objectives of the regime as per the table on p7 i.e. safe, timely, and convenient access to therapeutics products, particularly for the most disadvantaged for whom the potential gains from such products are the highest.

56. It is consistent with prescribing being part of the medical practitioners' scope of practice: all doctors may prescribe but only within boundaries.

57. Similarly, we support the category of designated prescriber for advanced practice in a specialty area, and expect to see this as Designated Nurse Prescriber rather than eg Diabetes Nurse Prescriber, Respiratory Nurse Prescriber, Child Health Nurse Prescriber etc. The specific details will be worked through by the RAs, but we mention it as the paper seemed to conflate advanced practice and scope of practice in relation to designated prescribers.

58. Standing orders can be problematic because of levels of inconsistency in their preparation and implementation nationally. The inability of nurse practitioners to issue Standing Orders has been a challenge, and we support changes to regulations enabling this.

59. The regulations do need to be reviewed, but Standing Orders fill an important gap at present, and will continue to be needed, though perhaps less often, as we transition to the new regulatory regime and nurse prescribing becomes more common.

- Do you support the proposal to shift the authorisation of prescribers into the detail of the scopes of practice for registered health practitioners (published by Responsible Authorities)? What are the advantages or disadvantages of this approach?
- Do you consider the consultation requirements to be adequate in the HPCA Act 2003 (refer Section 14 or table above)? Outline what, if anything, needs to change?
- What disputes have arisen with respect to scopes of practice in the past? Do further mechanisms for the resolution of disputes need to be considered? What should they entail (eg, use of an appointed panel)? (Refer Section 127 and 128 of the HPCA Act 2003.)
- Are the provisions in the HPCA Act 2003 to prevent an individual from prescribing (when deemed necessary) sufficient?
- Who needs to be able to share information with respect to prescribing or dispensing activity of concern? Are the protocols and accountabilities with respect to sharing information well understood? What needs to be improved, clarified or widened?

60. As above, we support shifting authorisation to the RAs and have outlined the advantages.

61. The consultation requirements set out in Section 14, HPCAA which mandate consultation with key stakeholders are sufficient, although as we have commented elsewhere, we note the need to strengthen interdisciplinary communication.

62. The HPCAA also provides for fair consumer representation in RAs, but does not mandate Māori representation. We believe it is important that this addressed because lack of Māori representation is a key structural discriminant (see (Human Rights Commission, 2012) which continues to drive disparate access to health interventions including therapeutic products and consequently entrenches health disparities. Equity is an important principle and objective which should be embedded throughout the new regulatory regime.

63. With regard to disputed scopes, NZNO objected to the introduction of the Nurse Assistant scope of practice, which after a considerable period, was taken to the Regulation Review Committee, and eventually resolved. We agree that processes for resolving disputes in a timely manner prior to publication of a scope or within a profession should be reviewed and clarified.

64. There was some controversy/contention around the Nurse Practitioner scope of practice and prescribing from other professions but this was managed appropriately.

65. We are confident that the RAs supported by the sector can manage and prevent an unsafe regulated health practitioner practising.

66. However, as noted previously, the HPCAA does not cover the unregulated workforce, which is rapidly expanding and increasingly encompasses clinical interventions. NZNO does not support regulation of unregulated care and support workers, but does recognise that regulations need to be comprehensive enough to deter inadvertent 'prescribing' and ensure that employers protect both clients and workers by appropriate training. We suggest the new legislation could outline penalties for those caught prescribing who are not regulated under the HPCA Act.

67. There should be robust mechanisms to ensure that all practitioners involved in the care of an individual know what medicines, products etc. have been prescribed. Shared E-records will support this, but we acknowledge there are still technical and privacy issues to resolve before these are embedded in practice. All medical information need not be available to all practitioners forever for instance; however, people must be aware at all times what information is available to which practitioner.

DELEGATED PRESCRIBERS

- Should a delegated prescriber category be retained in the new regulatory regime?
- Are there current or future service gaps or models of care that would lend themselves to delegated prescribing? Would amendments need to be made to the current delegated prescribing arrangements?
- If scopes of practice are used to authorise prescribing in the new regulatory arrangements, then a scope of practice could also identify who could prescribe on a delegated basis (and who could authorise a delegated prescribing order), including the training and competence requirements for doing so. What do you think of this option?
- Are there alternate prescribing arrangements to the delegated prescribing model that would better suited? For example, the use of

clinical management plans such as in the UK that require patient agreement (refer paragraph 56).

68. We do not anticipate the delegated prescriber category being used for nursing. NC is developing two levels of independent nurse prescribing - community nurse prescribing and specialty nurse prescribing. Nurses are accountable to the RA for their prescribing practice, which is quite different from a delegated prescriber who depends on an individual authorised prescriber to approve him/her.

69. With ~50,000 nurses, it would be impractical, time-consuming and costly to independently authorise each individual delegated prescriber.

70. However, we are aware that other professions whose practice circumstances differ have a different view, so we are not opposed to retaining the category.

- How might Standing Orders work better in the future? What needs to change?
- Please outline in detail any particular concerns you have with the current use of Standing Orders and consider possible solutions.

71. Standing Orders when well-run provide a great training opportunity for the community level prescriber. The ability to move to auditing rather than countersigning every supply has been a great improvement. When auditing is considered appropriate and safe for the practitioner and patient, it signifies a practitioner is ready to prescribe

72. Standing orders are a useful tool and NZNO would welcome engagement in the work around the review.

DISPENSING

- Are there particular issues you have with the parameters for regulating dispensing as noted in paragraphs 65 to 67?

73. Please note our earlier comments (Clauses 25-26) re access issues with dispensing afterhours, and the complexities around interpreting what constitutes dispensing.

74. The latter can differ substantially depending on the service and practitioners involved. For example, some District Nurses have been advised that drawing up a prescribed palliative care medication for a family member to administer during the night constitutes dispensing, while others have been advised that it is acceptable since the medication has already been dispensed by a pharmacist.

75. The management of people's pain and conditions should not be dependent on varying 'interpretations'. We suggest there are situations

such as the above, or where nurses are dispensing medications obtained by practitioner supply order, where either nurses should be able to dispense or it should be clarified that what they are doing is not dispensing.

DEVELOPMENTS TO SUPPORT THE REGULATORY FRAMEWORK

- Are there other key non-regulatory developments you consider important to support a new therapeutic products regulatory regime?
- Please raise any further aspects as you see fit

76. If there is a universal pathway for prescribing, this will almost certainly be medically directed. Where this has occurred e.g. c- Quip Colposcopy, nurses have largely been “shut out” and accessing the process has been made very difficult.

77. This must be guarded against to promote nurse prescribing and more timely and equitable access to medicines. The precursors and interfaces need to be looked at by Nursing Council, the profession and tertiary providers to ensure that the pathway is supportive of nurses and links seamlessly into the required prescriber requirements.

CONCLUSION

78. Access to appropriate and affordable therapeutic products is fundamental to modern health care. Prescribing is a tool that can be used in health care provided by a variety of regulated practitioners and health providers. Rapid changes in health require a regulatory regime that is robust, safe, flexible and responsive; the HPCAA meets these criteria for workforce regulation.

79. Nurses, as the largest body of regulated practitioners who are in every health setting throughout the country, are well positioned to provide safe and timely access to therapeutic products, particularly to those who have the least access and have the most to health benefit to gain.

80. We welcome and support the direction proposed by this document and look forward to working with you to expedite a comprehensive and flexible regime for prescribing and dispensing.

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REFERENCES

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