Draft Health Practitioner Regulation (New South Wales) Regulation 2016

Regulatory Impact Statement

REGULATORY IMPACT STATEMENT

TITLE OF REGULATORY PROPOSAL:	**Consultation Draft Health Practitioner Regulation (New South Wales) Regulation 2016**
PROPONENT:	**NSW Ministry of Health**
RESPONSIBLE MINISTER:	**Minister for Health**
RELEVANT ACT:	**Health Practitioner Regulation National Law (NSW)**

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1. The current Health Practitioner Regulation (New South Wales) Regulation 2010

The Health Practitioner Regulation (New South Wales) Regulation 2010 (2010 Regulation) facilitates the operation of the NSW specific provisions of the Health Practitioner Regulation National Law (NSW) (NSW National Law).

The NSW National Law implements in NSW the national registration and accreditation (NRAS) scheme for health practitioners. As part of NRAS, there is a national scheme for the registration of health practitioners across all the States and Territories. All States and Territories other than NSW and Queensland also have consistent provisions relating to the health, conduct, performance and complaints handling in respect of registered health practitioners that involve the relevant National Board, such as the Medical Board of Australia. However, NSW and Queensland are "co-regulatory" jurisdictions and have their own complaints handling provisions.

NSW kept its own specific complaints handling framework which involves 14 health professional Councils and the independent Health Care Complaints Commission. Provisions relating to complaints handling are mostly set out in the NSW specific provisions in Part 5A and 8 of the NSW National Law. There are also NSW specific provisions relating to the pharmacy profession.

The 2010 Regulation facilitates the operation of the NSW National Law. Many of the provisions of the 2010 Regulation are machinery in nature, such as setting out the composition of the Councils. However, there are also more substantive provisions relating to setting infection control standards for certain registered health professions, record keeping requirements for medical practitioners and provisions relating the pharmacy profession and pharmacy premises.

2. Why is the Regulation being reviewed?

The Subordinate Legislation Act 1989 provides for regulations to have a limited life. In most cases, regulations are automatically repealed after 5 years. When a regulation is due for repeal, the responsible agency must review the regulation, its social and economic impacts, and the need for the regulation. The agency must then make a decision about whether the regulation should be remade. The results of this review are required to be published in a Regulatory Impact Statement (RIS) and submissions invited from the public.

This RIS proposes that the existing 2010 Regulation be remade, subject to minor amendment, in the form of the draft Health Practitioner Regulation (New South Wales) Regulation 2016 (Draft Regulation). However, there are a number of issues about which the Ministry would like to hear submissions before a final decision on the provisions of the Draft Regulation is made.

3. Approach taken in this regulatory impact statement

This RIS serves two purposes associated with the Draft Regulation:

i) to meet the requirements of the Subordinate Legislation Act 1989 in terms of a RIS; and
ii) to serve as a Better Regulation Statement in accordance with the requirements of the Government's Guide to Better Regulation.

The Subordinate Legislation Act intends to ensure that new regulations benefit the community. To demonstrate that, the proponent agency must generally prepare and publish a RIS that articulates the objectives of the proposed regulation and considers a range of options to achieve those objectives. A RIS must also consider the economic and social costs of the proposed regulation with only that option which produces the greatest net benefit to the community being chosen. Parliamentary Counsel has certified that certain aspects of the Draft Regulation, being Parts 1 and 5 and Schedules 1 and 2, are machinery matters. Accordingly, the RIS does not look at these provisions in detail. However, submissions will still be accepted and considered on these provisions.

The Guide to Better Regulation identifies seven principles that characterise good Regulation. The principles are:

1) the need for government action should be established,
2) the objective of government action should be clear,
3) the impact of government action should be properly understood by considering the costs and benefits of a range of options, including non-regulatory options,
4) Government action should be effective and proportional,
5) consultation with business and the community should inform regulatory development,
6) the simplification, repeal, reform or consolidation of existing regulation should be considered, and
7) regulation should be periodically reviewed, and if necessary reformed to ensure its continued efficiency and effectiveness.

To demonstrate adherence to these principles when proposing a new regulation, the proponent agency must prepare a better regulation statement (BRS). A BRS must identify and justify compliance costs and show the action taken to minimise these costs. This RIS also serves as a BRS.

4. Consultation and Submissions on the Draft Regulation

Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services Branch
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions may also be made via email to legalmail@doh.health.nsw.gov.au. Submissions must be received by **15 June 2016**.

Individuals and organisations should be aware that generally any submissions received may be made publically available under the Government Information (Public Access) Act 2009. The Ministry of Health, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

5. Draft Health Practitioner Regulation (New South Wales) Regulation

The objectives of the Draft Regulation are to support the smooth operation of the NSW specific provision of the NSW National Law. The objects of the NSW National Law are set out in s3 of the NSW National Law and are nationally consistent objectives:

(1) The object of this Law is to establish a national registration and accreditation scheme for—
(a) the regulation of health practitioners; and
(b) the registration of students undertaking—
(i) programs of study that provide a qualification for registration in a health profession; or
(ii) clinical training in a health profession.

(2) The objectives of the national registration and accreditation scheme are—
(a) to provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered; and
(b) to facilitate workforce mobility across Australia by reducing the administrative burden for health practitioners wishing to move between participating jurisdictions or to practise in more than one participating jurisdiction; and

(c) to facilitate the provision of high quality education and training of health practitioners; and

(d) to facilitate the rigorous and responsive assessment of overseas-trained health practitioners; and

(e) to facilitate access to services provided by health practitioners in accordance with the public interest; and

(f) to enable the continuous development of a flexible, responsive and sustainable Australian health workforce and to enable innovation in the education of, and service delivery by, health practitioners.

(3) The guiding principles of the national registration and accreditation scheme are as follows—

(a) the scheme is to operate in a transparent, accountable, efficient, effective and fair way;

(b) fees required to be paid under the scheme are to be reasonable having regard to the efficient and effective operation of the scheme;

(c) restrictions on the practice of a health profession are to be imposed under the scheme only if it is necessary to ensure health services are provided safely and are of an appropriate quality.

In addition, there is a NSW specific objective in s3A of the NSW National Law, being:

In the exercise of functions under a NSW provision, the protection of the health and safety of the public must be the paramount consideration.

The Draft Regulation relates to:

- Infection control standards for certain professions,
- Record keeping requirements for the medical practitioners,
- Provisions relating to pharmacists and pharmacy premises, and
- Membership of the health professional Councils

The RIS will consider in detail the objectives and rationale for the different parts of the Draft Regulation, the alternatives to the Draft Regulation and the costs and benefits of both the Draft Regulation and the alternatives to the Regulation. Matters relating to the membership of the health professional Councils are machinery in nature. While the RIS does not consider these provisions in detail, the composition of the Councils is considered in Part 9.

6. Infection control – Part 2

Part 2 of the Draft Regulation requires "relevant health practitioners" to comply with the infection control standards in Schedule 3 of the Draft Regulation. A relevant health practitioner is:

- a medical practitioner,
- a nurse or midwife,
- a pharmacist, and

- a physiotherapist

The standards in Schedule 3 set out requirements relating to: hand and skin cleaning and the use of gloves; taking precautions to avoid direct exposure to a patient's blood or body substance; the use of protective gowns, aprons, masks and protective eye wear; the use and disposal of sharps; the disinfection and sterilisation of equipment and use of certain single use equipment; and clinical waste disposal.

The infection control requirements are included in the Draft Regulation in order to minimise the occurrence of infection, particularly blood borne infections, through health procedures, particularly procedures that penetrates the skin or other exposure prone procedures.

It is noted that the definition of "relevant health practitioner" is the same as the definition used in the 2010 Regulation except that podiatrists are no longer included in the definition. This is because podiatrists are subject to infection control guidelines set by the Podiatry Board of Australia[1]. Where a health profession is subject to infection control standards or guidelines issued by the relevant National Board, it is not considered appropriate for the Draft Regulation to impose additional obligations relating to infection control.

While it is not appropriate to impose infection control obligations on professions that are subject to infection control standards or guidelines issued by the relevant National Board, it is noted that not all professions who are not subject to such guidelines or standards are included in the definition of relevant health practitioner. The following professions are not subject to infection control guidelines or standards under either the Draft Regulation or by a National Board:

- Aboriginal and Torres Strait Island health practice,
- Chinese medicine,[2]
- Chiropractic,
- Medical radiation practice,
- Occupational therapy,
- Optometry, and
- Psychology.

The infection control requirements in the Draft Regulation are primarily about the guidelines to follow when a practitioner is conducting an exposure prone procedure. However, the standards can also be relevant when a practitioner comes into direct physical contact with a patient. While many of the above professions are unlikely to routinely be

[1] The Podiatry Board of Australia has issued infection control guidelines: http://www.podiatryboard.gov.au/Policies-Codes-Guidelines.aspx

[2] The Chinese Medicine Board of Australia has issued infection control guidelines in relation to acupuncture but not more broadly (http://www.chinesemedicineboard.gov.au/Codes-Guidelines.aspx).

involved in exposure prone procedures, many (but not all) of the above professions would routinely come into direct physical contact with patients.

In order to ensure that appropriate infection control procedures are followed, the Ministry would like to hear submissions on whether the infection control guidelines should be expanded to any other professions that are not bound by guidelines or standards relating to infection control set by the relevant National Board.

Issues for consideration?

1) Is the definition of "relevant health practitioner" in the Draft Regulation appropriate?
2) Are there any other registered health professions that should be required to follow the infection control standards in the Draft Regulation?

6.1 Objectives of Part 2 and the case for government intervention

The rationale for regulatory intervention is to reduce the risk of transmission of blood borne pathogens such as HIV and hepatitis B and C, as well as bacterial infections such as *Staphylococcus aureus*, by ensuring relevant health practitioners comply with appropriate infection control standards.

There is currently no vaccination against the blood borne conditions HIV and hepatitis C. The consequence of being infected with hepatitis B or C or HIV is long term and may result in debilitating illness. For example, hepatitis B or C may result in chronic hepatitis, and cirrhosis of the liver. In a proportion of cases this will progress to cancer, which is often fatal. Ensuring that health practitioners follow appropriate infection control requirements provides a strong measure of protection against the transmission of disease.

There is a real risk of infection of blood borne viruses following a needle stick injury involving an infected patient or health care worker. Where a needle stick injury occurs and the needle contains infected blood, the rate of transmission is 0.3% for HIV, 0-7% for hepatitis C, and between 6-30% for hepatitis B, depending upon the viral load and the nature of the penetration.[3] Thus, even where there is a direct transmission of infected blood, the rate of infection is relatively low but still significant.

More commonly, transmission of infections, including *Staphylococcus aureus*, multiresistant bacteria and viruses that can cause diseases, including skin infections, gastroenteritis, respiratory infections, and septicaemia, can be passed between health care workers and

[3] Australian National Guidelines for the Management of Health Care Workers Known to be Infected with Blood-Borne Viruses. Communicable Disease Network of Australia 2012. http://www.health.gov.au/internet/main/publishing.nsf/Content/36D4D796D31081EBCA257BF0001DE6B7/$File/Guidelines-BBV-feb12.pdf

patients by direct contact unless good infection control practices (including hand hygiene) are followed.

The consequences of transmission can be devastating, leading to serious disease and consequential costs to an individual, their family and the greater community (due to increased health costs). Further, these risks can be mitigated by simple infection control requirements.

Accordingly, the objective of Part 2 is to require relevant health practitioners to follow appropriate infection control procedures so as to minimise the risk of transmission of disease.

6.1.1 Costs and benefits of Part 2

Registered health practitioners would generally owe their patients a duty of care and have professional duties to act with good care toward patients. This would extend to complying with appropriate infection control requirements. Accordingly, Part 2 is not seen as imposing any additional economic costs on practitioners that they otherwise would not incur.

In respect of the benefits, Part 2 sets out specific requirements that all practitioners of the relevant professions must comply with, which helps ensure a good standard of infection control practice by all practitioners of the relevant professions. Further, the detailed requirements can assist in investigating, responding and, if necessary, prosecuting breaches of the requirements. In essence, the benefit of Part 2 is that in setting infection control requirements, practitioners are clearly aware of what is required of them and provides health professional Councils and the Health Care Complaints Commission a standard to assess complaints relating to poor infection control processes against.

6.2 Alternatives to Part 2

As noted above, both the Subordinate Legislation Act and the Better Regulation Principles require consideration to be given to alternative options to regulation. The alternatives to Part 2 of the Draft Regulation are considered below.

6.2.1 Option 1 – No regulation

Under this option, the Draft Regulation would not contain any specific provisions relating to infection control. Under this option the adoption of infection control requirements for the relevant professions would largely be controlled through notions of professional responsibility (and insurance premiums). That is, as professionals, registered health practitioners owe their patients a duty of care, and this would extend to ensuring that appropriate infection control practices are followed. Breaches of this requirement would be dealt with in via the health care complaints processes in the NSW National Law and the Health Care Complaints Act 1993 and could lead to a practitioner having conditions on their registration and, in serious cases, the loss of their registration and ability to practice.

6.2.1(a) – costs and benefits of Option 1

There are no direct financial costs to practitioners in respect of Option 1. Practitioners would still be bound by general professional standards and duties to comply with appropriate infection control guidelines. However, as the National Board for relevant professions have not set any infection control guidelines, and there would be no standards in the Draft Regulation, practitioners would need to find, consider and apply for themselves the appropriate standards. This is likely to lead to indirect costs to practitioners, patients and the public. Practitioners would need to spend time considering their professional obligations relating to infection control. As there are no relevant guidelines or requirements applying, the application of infection control processes may vary between practitioners and could result in a lowering of standards and/or inconsistent standards. This could lead to increased transmission of diseases, causing costs to the health care system and individual patients.

Further, if there were no infection control standards in the regulation, if a complaint is made against a practitioner regarding poor infection control procedures, the health professional Council or the Health Care Complaints Commission would not have a general standard to assess practitioners against. This may make it more difficult to assess complaints relating to poor infection control practices, leading to poorer management of complaints.

6.2.2 Option 2 – Require compliance with NHMRC infection control policies

Under this option, the Draft Regulation would continue to require relevant professions to comply with infection control requirements, but instead of setting out detailed requirements in Schedule 1, the Draft Regulation would require relevant health practitioners to comply with other relevant standards, such as the National Health and Medical Research Council's *Australian Guidelines for the Prevent and Control of Infection in Healthcare*[4]. These guidelines are useful, comprehensive and deal with much the same matters as Schedule 3 of the Draft Regulation.

6.2.2(a) Costs and benefits of Option 2

As registered health practitioners from a relevant profession would generally owe their patients a duty of care and have professional duties to act with good care toward patients, which would extend to complying with appropriate infection control requirements, Option 2 is not seen as imposing any additional economic costs on practitioners that they otherwise would not incur.

4 https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cd33_infection_control_healthcare_140616.pdf

There are benefits to Option 2. The NHMRC guidelines are detailed, are national guidelines and provide a good standard of infection control practices that could also be used as a standard against which a health professional Councils and the Health Care Complaints Commission could assess complaints relating to poor infection control processes. However, the NHMRC guidelines are guidelines and are therefore not always framed in terms of mandatory requirements. This may make it slightly more difficult to use as a standard to assess complaints relating to poor infection control processes.

6.3 Evaluation of the options

Good infection control practices are vital in reducing the risk of transmission of disease. This is particularly the case when a practitioner undertakes risky or invasive procedures.

All registered health practitioners would have a professional obligation to ensure that appropriate infection control practices are used. As such, it could be argued that Option 1 (no regulation) could be pursued as professional duties and responsibilities mean that it is not necessary to specify in the Draft Regulation the infection control practices with which practitioners must comply. However, that would leave practitioners from the relevant professions without any detailed standards to follow and could lead to poorer health outcomes and make it more difficult to assess complaints against health practitioners. This is not considered to be in the public interest. Accordingly, Option 1 is not supported.

The proposed Part 2 and Option 2 (the NHMRC guidelines) are similar in that both would set out in the Draft Regulation that practitioners must comply with particular standards. However, the proposed Part 2 in the Draft Regulation and Option 2 differ in what are those standards. Option 2 would apply the NHMRC guidelines while the proposed Part 2 would continue the existing standards relating to infection control. Both would set appropriate infection control standards and provide a standard against which to assess complaints. However, on balance it is considered that the proposed Part 2 in the Draft Regulation is more appropriate. This is because the standards are more detailed (making it easier to assess complaints) and practitioners are already subject to these requirements which should assist with compliance. That said, it is considered that the proposed Part 2 of the Draft Regulation and Option 2 are finely balanced and so submissions are sought on whether the Draft Regulation should retain the requirements in Part 2 or require compliance with the NHMRC guidelines.

Issues for consideration?

3) Should relevant health practitioners be required to comply with the infection control standards in Schedule 3 or the NHMRC's *Australian Guidelines for the Prevent and Control of Infection in Healthcare*?

7. Part 3 – Matters relating to the medical profession – record keeping requirements

Part 3 and Schedule 4 of the Draft Regulation sets out the record keeping requirements for medical practitioners and medical corporations. This Part and Schedule:

- Requires medical practitioners and medical corporations to keep records and sets out the matters that must be included in the medical record, and
- Sets out when a record is to be made and the storage and disposal requirements relating to medical records.

The proposed Part 2 and Schedule 4 are generally consistent with the existing requirements in the 2010 Regulation.

7.1 Objectives of Part 3 and the case for government intervention

Good record keeping requirements are essential for proper medical care. Accurate, up to date, legible and comprehensives records are essential to ensure proper, effective and safe care. This is so not just so that a practitioner can have an accurate record of previous diagnoses and treatment given to a patient (which in many cases will be relevant to current and future treatment decisions), but also so that other clinicians involved in a patient's care, such as if a patient's care is shared or a patient's care is transferred from one practitioner to another, can be aware of treatment decisions and a patient's history. Good record keeping is also essential so that patients themselves can, if they chose, access their medical records.

7.1.1 Costs and benefits of Part 3

Medical practitioners would generally owe their patients a duty of care and have professional duties to act with good care toward patients, which would extend to keeping up-to-date, accurate and comprehensive records. As such, Part 3 is not seen as imposing any additional economic costs on practitioners that they otherwise would not incur.

In respect of the benefits, Part 3 sets out specific requirements relating to record keeping that all medical practitioners and medical corporations must comply with, which helps ensure a consistent and good standard of record keeping by all medical practitioners. Further, by setting out detailed requirements, this can assist in investigating, responding and, if necessary, prosecuting breaches of the requirements. In essence, the benefit of Part 3 is that in setting out the record keeping requirements, medical practitioners are clearly aware of what is required of them and provides health professional Councils and the Health Care Complaints Commission a standard to assess complaints relating to poor record keeping against. Another benefit of Part 3 is that these are the current standards that apply to medical practitioners and therefore practitioners should already know what standards apply which assist in compliance.

7.2 Alternatives to Part 3

The alternative to Part 3 of the Draft Regulation is considered below.

7.2.1 Option 1 – no regulation

Under this option, the Draft Regulation would not set out the specific requirements relating to record keeping for medical practitioners. Medical practitioners would still have a professional obligation to keep appropriate records, but the standard required would not be set out in legislation.

7.2.1(a) Costs and benefits of option 1

There are no direct financial costs to medical practitioners in respect of Option 1. Practitioners would still be bound by general professional standards and duties to keep records. However, if the Draft Regulation did not set the standards of record keeping, medical practitioners would need to find, consider and apply for themselves the appropriate record keeping standards. This is likely to lead to indirect costs to practitioners, patients and the public. Practitioners would need to spend time considering their professional obligations relating to record keeping and, as there are no standards in the Draft Regulation, record keeping requirements may vary between practitioners which could result in a lowering of standards.

Further, as no record keeping standards apply, if a complaint is made against a practitioner regarding poor record keeping, the health professional Council or the Health Care Complaints Commission would not have a general standard to assess practitioners against. This may make it more difficult to assess complaints, leading to poorer management of complaints.

7.3 Evaluation of options

Good record keeping by medical practitioner is vital to good clinical care and practice.

All medical practitioners would have a professional obligation to ensure that appropriate records are kept. As such, it could be argued that Option 1 (no regulation) could be pursued as professional duties and responsibilities would arguably mean that it is not necessary to specify record keeping obligations in the Draft Regulation. However, that would leave medical practitioners without any detailed standards to follow. This could lead to poorer health outcomes and make it more difficult to assess complaints against health practitioners. Such an approach is not considered to be in the public interest and therefore Option 1 is note supported.

On the other hand, having the record keeping obligations set out in the Draft Regulation will ensure that practitioners are aware of the standards that are expected of them. This will assist with compliance with record keeping requirements and provide a standard against

which to assess complaints relating to poor record keeping. Accordingly, it is considered appropriate to maintain the standards set out in Part 3 of the Draft Regulation.

8. Part 4 – provisions relating to pharmacy practice and pharmacy premises

Schedule 5F of the NSW National Law limits, except in limited circumstances, a person other than a pharmacist from having a pecuniary interest in a community pharmacy business and requires the Pharmacy Council to approve the registration of a holder a pecuniary interest[5]. Further, Schedule 5F requires pharmacy businesses to be licensed by the Pharmacy Council and prevents the Pharmacy Council from approving premises to operate as a pharmacy premises if the premises fails to comply with the standards prescribed by the regulations.

The Draft Regulation sets the prescribed standards for pharmacy premises and professional services rooms. These standards generally replicate the existing standards that apply in the current Regulation.

Accordingly, clause 12 of the Draft Regulation provides for the following standards for premises other than professional services rooms:

- at least one doorway allowing direct public access to the premises is to be provided,
- the premises, including any doors, windows, floors or ceilings, are to be secure so as to minimise the risk of unauthorised access to the premises and scheduled medicine on the premises,
- the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Pharmacy Council may approve in a particular case,
- there is a part of the premises in which a consultation conducted by a pharmacist is not reasonably likely to be overheard by a person not party to the consultation,
- the premises are to be equipped with:
    - the equipment listed in Schedule 5 of the Draft Regulation, and
    - any other equipment necessary to ensure the safe and competent delivery of the pharmacy services delivered in those premises,

  installed and maintained in accordance with the manufacturer's instructions or if no such instructions exist, to the standard necessary for the safe and competent delivery of pharmacy services,
- the publications listed in Schedule 5 are to be kept in the premises or are to be accessible by electronic means from the premises.

Schedule 5 requires premises to be equipped with:

- a refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines,

[5] Schedule 5F does not apply to pharmacies located in public hospitals

- a dispensing balance,
- heavy duty scales, capable of weighing up to 1 kg and a set of metric weights compatible for use with those scales or an electronic scale capable of weighing up to 1 kg in increments of no more than 50 mg,
- a 200 mL dispensing measure,
- a 100 mL dispensing measure,
- a 10 mL dispensing measure,
- a 5 mL dispensing measure,
- a funnel,
- 2 mortars and pestles (at least 1 of the mortars and pestles being made of glass),
- a stirring rod,
- 2 spatulas,
- an ointment slab, and
- a tablet counting tray.

In addition, Schedule 5 requires pharmacy premises to have the following publications:

- the *Poisons and Therapeutic Goods Act 1966* and the regulations under that Act
- the Poisons List proclaimed under section 8 of the *Poisons and Therapeutic Goods Act 1966* or the latest edition, and all published amendments or supplements to that edition, of the *Guide to the New South Wales Poisons Schedules* published by the Pharmacy Guild of Australia (New South Wales Branch),
- the Health Practitioner Regulation National Law (NSW) and this Regulation, and
- the latest editions, and all published amendments or supplements to those editions of the publications listed in the Pharmacy Board of Australia's *Guidelines on practice-specific issues – Guidelines 1 (List of reference texts for pharmacists).*

Additional standards are also set out for dispensing areas, being that the area:

- is to be adequately lit and ventilated,
- is to have adequate heating facilities for dispensing and compounding drugs,
- is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,
- is to have a bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, and that has an impervious covering, and
- is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

For professional services rooms, the Draft Regulation sets out the following standards:

- all reasonable steps to prevent public access to the premises are to have been taken,

- the premises, including any doors, windows, floors or ceilings, are to be secure so as to minimise the risk of unauthorised access to the premises and scheduled medicine on the premises,
- the premises are to be equipped with a dispensing area of at least 8 square metres or such lesser area as the Pharmacy Council may approve in a particular case,
- the premises are to be laid out and equipped so that:
    - any drug stored in the premises can be stored in accordance with the relevant drug's storage conditions, and
    - all the drugs being prepared, packaged or stored in the premises, for supply to a particular patient or to a health care facility for supply to a particular patient or resident of that facility, can be stored together, and
    - any documentation physically stored in the premises relating to that patient or resident can be stored with those drugs,
- the publications listed in Schedule 6 are to be kept in the premises or are to be accessible by electronic means from the premises in accordance with clause 15.

Where there is a dispensing area, the Draft Regulation also sets the following standards regarding the area:

- it is to be adequately lit and ventilated,
- it is to be equipped with a stainless steel or similarly impervious sink that has an impervious surround and is supplied with hot and cold running water,
- it is to have a bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, and that has an impervious covering, and
- it is to have at least one dispensary barcode scanner connected to each dispensing station in the dispensing area.

8.1 The objectives of Part 4 and the case for government intervention

Part 4 is aimed at ensuring that there are appropriate standards to apply to pharmacy premises and gives effect to Schedule 5F of the NSW National Law, which prevents the Pharmacy Council from licensing a premises as a pharmacy premises unless the standards in the regulation are met. The licensing of a pharmacy business helps to protect the public by ensuring that there is appropriate oversight by the Pharmacy Council of pharmacy businesses and ensures that the Council has the means to ensure pharmacists apply those standards. The standards in the Draft Regulation help ensure that premises are appropriate and safe for pharmacy practice and thereby assists in protecting the public.

8.1.2 Costs and Benefits of Part 4

The standards for pharmacy premises in Part 4 of the Draft Regulation set out the requirements of the premises, such as having a private consultation area to ensure privacy

for consultations and having secure doors and windows in order to minimise the risk of theft of medicines, as well as the equipment and publications that pharmacy premises require to carry out pharmacy practice. The benefit of Part 4 is that it ensures that pharmacy premises are appropriately structured, maintained and equipped so as ensure a pharmacy practice can be carried out safely and professionally. The standards are quite prescriptive, particularly in terms of the equipment required, which has the benefit of ensuring that the standards can be easily understood and complied with by pharmacists and enforced by the Pharmacy Council.

However, there are costs associated with the standards in Part 4. The prescriptive standards in Part 4 relating to the building requirements create costs in relation to the commissioning of a pharmacy premises. That said, the costs associated with complying with the Draft Regulation, as opposed to the general costs associated with buying a pharmacy premises, are difficult to quantify but are considered to be minimal. In addition, the specific equipment premises are required to hold under the standards results in costs to pharmacists in having to purchase the equipment. In general, these costs are considered to be minimal as pharmacists are likely to require at least some of the equipment regardless of whether the Draft Regulation required the premises to be so equipped. However, the prescriptive nature of some of the equipment required is arguably redundant or not justified. For example, much of the equipment listed in Schedule 5 relates to equipment used in relation to compounding of pharmaceutical products, such as:

- a dispensing balance,
- a funnel,
- 2 mortars and pestles (at least 1 of the mortars and pestles being made of glass)
- a stirring rod,
- 2 spatulas, and
- an ointment slab.

Compounding of pharmaceutical products has become more of a specialised field and there are many pharmacists who would rarely carry out compounding other than simple compounding such as preparation of a cream for example. Further, the Pharmacy Board of Australia has guidelines relating to compounding that require pharmacists that carry out compounding to have appropriate equipment, with the appropriate equipment dependent on the sort of compounding undertaken (eg simple or complex compounding)[6]. As such, it may no longer be appropriate or necessary for the Draft Regulations to require all pharmacies to be equipped with specific equipment relating to compounding.

[6] Guidelines on compounding of medicines, Pharmacy Board of Australia, http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx

8.2 Alternatives to Part 4

The alternatives to Part 4 of the Draft Regulation are considered below.

8.2.1 Option 1 – No regulation

Under this option, there would be no standards in the Draft Regulation. In essence, this would mean that there would be no standards to assess an application for a pharmacy premises against and therefore no basis for the Pharmacy Council to refuse an application for a pharmacy premises (other than the fact that the owner was not a pharmacist).

8.2.1(a) Costs and benefits of option 1

If there were no standards set out in the Draft Regulation, pharmacists would still be under a professional obligation to ensure that their premises where maintained and equipped in a safe and professional manner. For professional reasons, it is expected that most pharmacists would continue to meet some, if not most, of the existing requirements that currently apply. However, if a pharmacist chose not to, the pharmacist could establish a poorly maintained and equipped premises, which is likely to result in potential harm to patients and the community (through potential increases in theft of medications, higher safety risks due to ill equipped premises). While complaints could be made and action taken against such pharmacists, this would result in a reactive rather than proactive safety regime and may impact on public health and safety.

8.2.2 Option 2 – less prescriptive standards

Another option is to retain Part 4 and Schedule 5, but include less prescriptive standards. For example, the list of equipment in Schedule 5 could only include equipment that would be expected to be required in all or most pharmacies (such as a refrigerator manufactured for the purpose of storing vaccines and a tablet counting tray). The equipment relating to compounding of pharmaceutical products would, under this option, no longer be a standard required by pharmacies under the Draft Regulation (though there would still be a requirement to have appropriate equipment as per the Pharmacy Board of Australia's guidelines, which may also mean that more comprehensive equipment is required, depending on the type of compounding undertaken).

8.2.2 (a) Costs and benefits of option 2

Under this option, the benefits and costs would be similar to the benefits accruing from the Draft Regulation. However, the costs may be lower for any pharmacist who is intending to establish a new pharmacy premise as the pharmacist would not need to incur costs purchasing the most of the equipment listed in Schedule 5 (which relates to the equipment used when compounding pharmaceutical products). This would be expected to save such pharmacists in the region of $2000-$3000. Of course, these costs savings would only apply if a pharmacist did not intend to carry out compounding. If a pharmacist was intending to carry out compounding, particularly complex compounding, these costs would still be

incurred regardless of the requirements in the Draft Regulation (further, where compounding would be undertaken more specialised equipment is likely to be required).

8.3 Evaluation of the options

Appropriately equipped, safe and secure pharmacy premises are important for public health and safety. The setting of standards required by pharmacy premises ensures there is appropriate oversight by the Pharmacy Council of pharmacy businesses. Appropriate standards help ensure that premises are appropriate and safe for pharmacy practice and thereby assist in protecting the public.

As Option 1 would remove any such standards, and thereby the oversight of the Pharmacy Council, Option 1 is not supported.

Part 4 of the Draft Regulation and Option 2 are similar in that both would set out the standards required for pharmacy premises. However, Option 2 would have less restrictive standards in relation to the equipment required of pharmacy premises. This would be expected to result in lower costs to pharmacists who do not carry out compounding of pharmaceutical products. Whether Option 2 or Part 4 of the Draft Regulation is the most appropriate option depends on whether pharmacists would routinely carry out compounding of pharmaceutical products. The Ministry's initial view is that compounding has become more of a specialised area and that most pharmacists would not routinely require equipment to undertake compounding. Further, where compounding equipment is required, the sorts of equipment will depend on the type and scope of compounding undertaken. Therefore, even when compounding occurs it may not be appropriate to list the exact equipment required and instead pharmacist should decide for themselves what they professionally require. Accordingly, the Ministry is leaning towards Option 2. However, the Ministry would like to hear submission on this issue before a decision is made.

Issues for consideration?

4) Should the pharmacy standards be less prescriptive regarding the equipment a pharmacy must hold in order to be registered?

9. Composition of the Councils

Schedule 1 of the Draft Regulation sets out the composition of the health professional Councils.

The composition of the Councils was reviewed in 2011 (following the release of a discussion paper) and a number of changes to the composition were made in 2012[7]. However, this RIS presents an opportunity to again consider whether the current composition of the 14 health professional Councils remains appropriate.

In this regard, it is noted that in respect of the Pharmacy Council, the current Regulation provides that the Council is made up of 10 members, 5 being appointed by the Governor and 5 being elected by the NSW pharmacists. Members serve for a 3 year period. Having elected members take their office from the day of being elected can create problems if an election is not held to coincide with the end of the terms of office of the previous elected members. Accordingly, to deal with any lacuna that may arise, the Draft Regulation provides that the elected members take office on 1 April after the election. However, the Ministry would like to hear submissions on whether this is an appropriate way to deal with the issue.

Moreover, the RIS provides an opportunity to consider whether elected members for the Pharmacy Council are still appropriate. Election of members provides an opportunity for practitioners to be nominated for membership of the Council by their peers. However, a health professional Council is established to hear and respond to complaints against health practitioners for the purpose of protecting the public and therefore elected members may not necessarily be most appropriately qualified or experienced to perform the role. Further, the costs, both in administrative time and fees to the Electoral Commission, associated with running an election represents a burden on the Council and the profession that could be reduced by having members selected for appointment by a more efficient method, in line with the appointment of members to the other Councils.

Issues for consideration?

5) Is the current composition of the health professional Councils appropriate?
6) Should any changes be made to the composition of the health professional Councils? In particular should the Pharmacy Council be comprised of elected members?

10. Summary

The Draft Regulation is intended to support the operation of the NSW National Law. The Draft Regulation includes provisions relating to the infection control standards that apply to relevant professions and record keeping requirements for medical practitioners. In addition, the Draft Regulation sets out the standards that apply to pharmacy premises and the members of the health professional Councils.

The Draft Regulation is based on the existing Regulation and is generally considered to be the most effective mechanism to support the NSW National Law. However, the Ministry would like to hear submissions on issues raised in this RIS.

[7] Health Practitioner Regulation (New South Wales) Amendment (Health Professional Councils) Regulation 2012

11. Organisations to be consulted

Aboriginal and Torres Strait Islander Health Practice Council of New South Wales
AHPRA
Australian Acupuncture and Chinese Medicine Association Ltd
Australian Dental and Oral Health Therapists' Association
Australian Dental Association of NSW
Dental Hygienists Association of Australia Inc. NSW Branch
Australian Dental Prosthetists Association (NSW)
Australian Institute of Radiography
Australian Medical Association (NSW Branch)
Australian Osteopathic Association
Australian Physiotherapy Association
Australian Podiatry Association NSW & ACT
Australian Psychology Association
Australian Salaried Medical Officers Federation of NSW
Avant Mutual Group
Chinese Medicine Council of New South Wales
Chiropractic Council of New South Wales
Chiropractors Association of Australia (NSW),
Consumers Health Forum of Australia
Dental Council of New South Wales
Guild Insurance
Health Care Complaints Commission
Health Consumers NSW! (HCNSW)
Health Services Union NSW
HPCA
Local Health Districts
MDA National
Medical Council of New South Wales
Medical Radiation Practice Council of New South Wales
Medical Services Committee
Meridian Lawyers
National Aboriginal and Torres Strait Islander Health Worker Association
NSW Nurses' Association
Nursing and Midwifery Council of New South Wales
Occupational Therapy Australia Ltd
Occupational Therapy Council of New South Wales
Optometrists Association of Australia – NSW Division
Optometry Council of New South Wales
Osteopathy Council of New South Wales
Pharmaceutical Society of Australia – NSW Branch
Pharmacy Council of New South Wales
Pharmacy Guild of Australia (NSW Branch)
Physiotherapy Council of New South Wales
Podiatry Council of New South Wales
Psychology Council of New South Wales
Statutory Health Corporations