Queensland Nurses & Midwives' Union

Submission to

The State Development, Natural Resources and Agricultural Industry Development Committee

Medicines and Poisons Bill 2019

Medicines and Poisons (Medicines) Regulation 2019

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Introduction

The Queensland Nurses and Midwives' Union (QNMU) thanks the State Development, Natural Resources and Agricultural Industry Development Committee (the Committee) for the opportunity to provide feedback on the *Medicines and Poisons Bill 2019* (the bill) and the *Medicines and Poisons (Medicines) Regulation* (the regulation).

Nursing and midwifery is the largest occupational group in Queensland Health (QH) and one of the largest across the Queensland government. The QNMU is the principal health union in Queensland covering all classifications of workers that make up the nursing workforce including registered nurses (RN), midwives, enrolled nurses (EN) and assistants in nursing (AIN) and personal care workers (PCW) who are employed in the public, private and not-for-profit health sectors including aged care.

Our more than 60,000 members work across a variety of settings from single person operations to large health and non-health institutions, and in a full range of classifications from entry level trainees to senior management. The vast majority of nurses and midwives in Queensland are members of the QNMU.

The bill and regulation are two of the most important pieces of health legislation affecting public health and safety in Queensland. We therefore question the appropriateness of referring them to this committee instead of the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee whose members are experienced in contemplating matters related to health.

The QNMU acknowledges the bill and regulation are an improvement of the previous drafts, however in providing feedback, the QNMU still has three major areas of concern. These are:

1. The use of Substance Management Plans (SMPs) as a core regulatory mechanism within the legislation;
2. Extended Practice Authorities (EPAs) which may impact on nurses and midwives;
3. The creation of an 'Aged Care Worker' entity able to administer a range of medications within the residential aged care environment.

These and related concerns will be addressed in detail in this submission.

The QNMU makes the following recommendations –

Recommendations

Medicines and Poisons Bill 2019

The QNMU recommends* -

Amend Section 18 (h) - Meaning of *deals* with a regulated substance - to read -

asks or directs another person to do something mentioned in any of paragraphs (a) to (g) **including if the substance is a medicine, by prescribing the medicine.**

Amend Section 20 - Meaning of regulated activity to read –

A **person carries out a** regulated activity ~~is~~ **if they are** –

(a) ~~a~~ dealing with a regulated substance; or

(b) a pest management activity.

Amend Section 23 – Meaning of possess a regulated substance – to read (as per the previous draft bill)

(1) Possess, a regulated substance, means have custody or control **including storing** of the substance.

Amend the title of Section 51 to 'Agents and **unpaid** carers'.

Include a definition of 'unpaid carer' in Schedule 1 - Dictionary to ensure those receiving a government carers' payment will not be prohibited from assisting their charge with their medication.

<u>Part 2 Substance Management Plans Sections 92-94</u>

- Provide an example or guidance on what constitutes a 'reasonable excuse' for non-compliance (section 93(1);
- Identify the authorised external document for lodging the SMP;
- Identify the authority that oversees quality control of SMPs;
- Identify the enforcement mechanism and responsible agency for non-compliance.

SMPs should be piloted in a health service or facility prior to any statewide implementation under this legislation.

Administrative Action Parts 3 and 4

Develop an education program for clinicians and the public.

Nominate the Office of the Health Ombudsman (OHO) under s127(b) – Statement of Warning - as the authorised agency to take action against offending health practitioners under existing processes.

Amend Section 238 - Delegation by chief executive - to read -

The chief executive may delegate the chief executive's functions and powers under this Act, other than under section 127, to an appropriately qualified person who is a health service employee or public service employee **and has authority to direct the practice of a class of persons.**

Amend Schedule 1 – Dictionary to include:

- a definition for 'therapeutic use';
- a definition of Chief Executive;
- a definition of 'unpaid carer'.

Medicines and Poisons (Medicines) Regulation 2019

The QNMU recommends –

Amend Section 24 – Administering under extended practice authority – to include a new sub-clause 24(3) that reads -

24(3) A registered nurse may administer a medicine or give a treatment under a clinical protocol.

Examples –

1. **A registered nurse practising in the area of sexual assault.**
2. **A registered nurse practising in the area of forensic medicines.**

Amend Section 27(1) Administering to read -

An enrolled nurse **supervised by a registered nurse** may administer a medicine to a patient under the direct ~~*supervision*~~ **observation** of a medical practitioner administering anaesthesia if it is reasonably necessary to ensure the safety of the patient before, or during, the patient's anaesthetic procedure.

Amend section 38 Oral or informal prescribing

to include –

a note clarifying if the section applies to all authorised persons or only to the person receiving the prescription.

to include –

procedures to follow if the prescription is not given nor the signature made by the next business day in respect to 38(3) below -

(2) The written prescription must be given, or the signature made, as soon as practicable but no later than the next business day after the medicine was administered.

Amend section 110 Review – Act s.93

to include –

(1) For section 93(3) (b) of the Act, a substance management plan must be reviewed – **by whom?**

Amend Schedule 7 Part 1 – 1 Definitions for schedule to include –

Enrolled Nurse **means an Enrolled Nurse who does not have a notation in respect to medicine administration on their registration.**

Amend all references throughout the regulation and schedules that state -

a registered nurse or nurse practitioner is *under the supervision* of a registrar, specialist medical practitioner or medical practitioner to read -

a registered nurse or nurse practitioner is *under the direction* of a registrar, specialist medical practitioner or medical practitioner.

Schedule 20 – Dictionary –

insert a new definition of *direction* to read -

Direction by a registrar, specialist medical practitioner or medical practitioner of a registered nurse or nurse practitioner means the oversight by the registrar, specialist medical practitioner or medical practitioner of the dealings of the registered nurse or nurse practitioner for directing, demonstrating and monitoring the dealings.

amend the definition of ***clinical protocol*** to read -

clinical protocol means a standing order applying in relation to an approved person performing a procedure or diagnostic test for practising any of the following professions—
(a) clinical perfusion;
(b) nuclear medicine technology;
(c) respiratory science;
(d) speech pathology;
(e) registered nurse

Further –

- There is no introduction of the 'aged care worker' through the caveat to schedule 13 of the regulations.

- QH develop a transition timeframe in consultation with relevant health unions.

* Deletions in ~~strikethrough~~, additions in **bold.**

Proposed Regulatory Scheme

Impact on Aged Care

The QNMU has considered the proposed regulatory scheme for medicines and poisons including the bill and regulation. Although there have been a number of improvements made to the previous draft bill and regulation, we continue to have major concerns that despite the apparent removal of 'aged care worker' provisions, the proposed regulation still provides an opportunity for these to be included.[1] Indeed, page 90 of the Explanatory Notes to the bill states –

> It is intended to prescribe aged care workers by regulation, with the detail of their requirements under the draft Medicines Regulation to be determined prior to making of the Regulation. Further refinement to the regulation of aged care workers under the Medicines and Poisons scheme may be needed following the Royal Commission into Aged Care Quality and Safety and the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's Inquiry into aged care, end-of-life and palliative care, and voluntary and assisted dying.

Over recent years a substantial number of inquiries, reports and now a Royal Commission have identified the aged care sector is experiencing systemic distress and a pervasive sense of crisis. Multiple and interrelated stressors across the sector require that any solutions must address a range of issues such as:

- the increasing frailty, acuity and care needs of those requiring aged care services;
- a deskilled workforce characterised by the loss of skilled nurses from the sector and an increase in unregulated care workers, all at a time that the care needs (including significant health care needs) of older Australians have never been greater;
- a workforce comprising a significant unregulated care worker component (77.01% in an audit of over eighty aged care facilities in Queensland by the QNMU in 2018), that appears to have been driven by providers looking for a low cost, lower skilled, compliant workforce, rather than one which focuses on client health and their broader care needs.

[1] See Schedule 13 Institutions and facilities, Part 1 Aged care facilities which notes – Policy changes to this part will be discussed with relevant stakeholders while the Medicines and Poisons Bill 2019 is considered by the Parliamentary Committee.

The QNMU is concerned this trend is part of a broader and deliberate strategy of replacing the aged care nursing workforce with a "quasi" nursing workforce ill-prepared to meet the often high complex care needs of older Australians.

Given the findings of the Royal Commission continue to expose the many problems associated with medication management, we can see no justification for introducing another level of unskilled worker into the aged care framework. This will only serve to exacerbate the current deficiencies in standards of care for older Queenslanders.

While jurisdiction for aged care matters rests largely with the Commonwealth, state-based medicines and poisons legislation and regulation have a significant impact on safe medication practice. As the peak professional and industrial body for nursing and midwifery in Queensland, the QNMU's aim is always to ensure the nursing and midwifery workforce is able to provide safe, quality care.

We seek an assurance from the committee there will be no introduction of the 'aged care worker' through the caveat in schedule 13 of the regulation.

Section 3 Main Purposes of the Act

In our view, the potential introduction of the aged care worker is distinctly at odds with the three main purposes of the Act (currently the bill).

Changes to medication management in aged care pose a substantial threat to public safety. Legitimising unsafe medication practice through legislation and regulation at a time when there is considerable scrutiny of aged care quality and safety is incongruous with widespread and legitimate concerns about this sector. The (then) Australian Aged Care Complaints Commissioner (2018) has already identified medication management as an area of significant and increasing complaints. There is potential for changes under the regulation to drive further complaints around unsafe practice.

In 2008, the Queensland Department of Health (DoH) considered the introduction of guidelines for aged care workers to assist with medications in residential aged care facilities. The Department sought the view of all Directors of Nursing of state government nursing homes at that time. The unanimous view of those senior members of the nursing profession working in aged care was that unregulated aged care workers should not be involved in medication practices, due to the high risk to resident safety. Unregulated aged care workers simply do not have the theoretical and practice knowledge to safely administer medications to a vulnerable, frail and often cognitively impaired cohort of older Australians.

As a result, QH recommended to the Chief Executive that guidelines for aged care workers in assisting with medication should not be introduced due to the risk to resident safety. Since that time, the Royal College of Nursing Australia, the Association of Gerontological Nurses and the Australian Nursing and Midwifery Federation jointly developed professional nursing practice standards for aged care workers to assist (only) those who self-administer their medicines in the aged care setting. The Federal Department of Health endorses these standards as a resource for RNs in residential aged care medication management. This standard is also formally endorsed by the Coalition of National Nursing and Midwifery Organisations (CoNNMO).

If the Committee determines aged care workers will be included in the regulation, we urge QH to comply with its duty of care, as defined in section 22 of the *Civil Liability Act 2003 (Qld).* We ask QH to respect the professional opinion of Queensland's aged care nursing leaders and that of the 54 national nursing and midwifery organisations that make up CoNNMO by giving unregulated aged care workers legislative authority to administer medicines **only** where the resident is assessed as competent to self-administer.

The introduction of aged care workers through the regulation will put the public at risk of harm, could put aged care workers at risk of civil action and could put RNs at risk of action under the *Health Practitioner Regulation National Law Act 2009* (the National Law) for failing to comply with accepted standards.

We can see aged care employers may have beneficial outcomes in reducing staffing costs and having low-skilled compliant workforces by employing unregulated carers to undertake medication management in place of registered and enrolled nurses, but health practitioners and consumers are likely to have negative outcomes.

As has been well described in the literature, a significant contributing factor to the Global Financial Crisis (GFC) in 2008 was the simplification and loosening of regulation in the financial sector with disastrous results. Health care is another critical area with significant impacts on society and individuals and the lessons from the GFC should not be lost in this context. It is highly likely the ongoing Aged Care Royal Commission will find regulatory failure has also contributed to the current crisis in aged care. Modernising and simplifying regulatory frameworks must not be an end unto itself.

Reducing a regulatory burden must be weighed against the potential risks to quality of care and those receiving it across settings, with a particular risk in the aged care sector and its vulnerable clients due to legitimising the "aged care worker" role. As the Financial Services Royal Commission has exposed, lack of a robust regulatory environment and a lethargic regulator(s) is a recipe for corporate bad behaviour and subsequent consumer harm.

The overriding lesson from the financial services sector must be that health and aged care providers simply cannot be trusted to follow regulation. Medication administration and management was the most frequent complaint area reported by the (then) Australian Aged Care Complaints Commission in the *2017/18 Annual Report* and this could only be anticipated to rise under the deregulation model proposed in this legislation.

Role of the EN, RN and Nurse Practitioner (NP)

There are a number of terms used throughout the bill and regulation that need clarification or amendment and definitions that have not been included. Some of these deficiencies reflect a general misunderstanding of the role of ENs, RNs and NPs, their scope of practice and the potential fallout for the public, particularly aged care. The QNMU urges the committee to protect the safety of older Queenslanders through this legislation by resisting any moves that will pose a potential risk to the public and the profession.

The current *Health (Drugs and Poisons) Regulations 1996* (HDPR) have been in place for 23 years. During this time there have been significant changes to nursing and midwifery regulation including:

- A national registration and accreditation scheme;
- Expanded standards of practice;
- New Codes of conduct;
- New Codes of ethics; and
- New Decision-Making Frameworks.

The nursing and midwifery professions' scope of practice is the full spectrum of roles, functions, responsibilities, activities and decision-making capacity that individuals within that profession are educated, competent and authorised to perform (NMBA,2013).

Definitions and understandings within the nursing and midwifery regulatory framework need to align with those set out in the bill and regulation. Our submission highlights those areas where there is potential conflict and other provisions for which we seek amendment or removal.

Medicines and Poisons Bill 2018

Major areas of Concern

Section 18 Meaning of *deals* with a regulated substance

Amend Section 18 (h) to read

asks or directs another person to do something mention in any of paragraphs (a) to (g) **including if the substance is a medicine, by prescribing the medicine.**

Section 20 Meaning of *regulated activity*

Amend Section 20 - Meaning of regulated activity to read –
A **person carries out a** regulated activity ~~is~~ **if they are** –

(a) ~~a~~ dealing with a regulated substance; or
(b) a pest management activity.

Section 23 Meaning of *possess* a regulated substance

Amend section 23 – Meaning of possess a regulated substance – to read (as per the previous draft bill)

(3) Possess, a regulated substance, means have custody or control **including storing** of the substance.

Section 51 Agents and carers

One of our main concerns with the previous draft bill and regulation were the provisions enabling aged care workers to administer medicines.

The current draft of the regulation has removed the aged care worker sections under the approved persons provisions (at least at this stage), however the bill retains section 51.

This section provides a defence for persons who '*for lawfully helping a patient, administers a medicine in accordance with the approved label of the medicine*'.

Section 51 does not apply to 'approved persons' who administer the medicine in an authorised way, so in our view, the original intent of section 51, when considering the

examples in the section, was to distinguish agents and carers from the aged care workers in the previous draft of the regulation.

Now aged care workers are no longer 'approved persons' in the current draft, a 'carer' by any name will be entitled to the above defence if they administer from dose administration aids (DAAs), or dispensed bottles, insulin pens, droppers, etc.

This section 51 now provides the same ambiguity as the current HDPR which has allowed aged care providers to test its regulatory limits in relation to medication administration by unregulated workers. We anticipate providers could use this section to justify their carers administering medicines unsafely because it is defensible.

The QNMU recommends section 51 of the bill be retitled to 'Agents and **unpaid** carers', regardless of the final outcome of the regulation.

A definition of 'unpaid carer' will also need to be added to the bill, to ensure those receiving a government carers' payment will not be prohibited from assisting their charge with their medication.

Part 2 Substance Management Plans - Sections 92-94

The bill introduces the SMP to assist with risk management of regulated activities and substances. Under section 92 (definitions for part) a SMP is a document setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at the regulated place.

In our view, the SMP is integral to operation of the bill and regulation. There are several factors that make the SMP itself a risky proposal.

Regulated places and responsible persons (as defined under section 92(b)) need much greater support and guidance in their formulation. The bill seems to assume the responsible person will somehow know how to prepare an SMP without the benefit of a model plan.

We believe there should be one recognised statewide standard SMP template written by the Therapeutic Goods Administration (TGA) in consultation with the Australian Commission on Quality and Safety in Health Care (ACQSHC) that can then form the basis of individual SMPs. Within this there should be a model minimum standard for each type of facility to ensure best practice across the state rather than a piecemeal individualised document. The QNMU is concerned that without such an approach, the system will be highly reliant on the capacity of

relevant entities to develop these plans, with the attendant risks of manipulation, variable standards, as well as safety and quality risks.

In our view, SMPs should be piloted in a health service or facility prior to any statewide implementation under this legislation to iron out any problems. We note:

- The SMP is a risk management strategy that only appears to be evaluated following an incident;
- Given the number of SMPs that would need to be developed, the QNMU believes timely review of these plans would be a considerable burden for the regulator or agency with oversight, which may be eased if SMPs were standardised. A core aspect of safety and quality in health care is the standardisation of processes to reduce variation and improve outcomes;
- There is no example or guidance on what constitutes a 'reasonable excuse' for non-compliance [section 93(1)];
- As there is the potential for workload matters or grievances to arise from any implementation of the SMP, there must be provisions enabling affected workers and their unions to be consulted during the development stage.

We also see a number of problems with the model of co-regulation for SMPs:

- The document is not lodged with any authorised external body;
- There is no apparent proactive oversight or quality control of the document;
- There is no apparent enforcement mechanism or agency identified to audit facilities or ensure compliance although there are penalties for non-compliance;
- If the DoH Medicines Regulation and Quality unit is charged with this role, it will need to be adequately staffed and resourced;
- It would be far more efficient to ensure compliance with the existing quality and safety standards.

<u>Administrative Action Parts 3 and 4</u>

This represents a significant change that requires an education program for clinicians and the public.

<u>Section 127 Statement of Warning</u>

The Minister, chief executive or chief health officer (each a senior administrator) may make a public statement identifying and giving warnings or information about, any of the following matters –

(c) Offences committed against a relevant law and the persons who committed the offences.

Section 127(2) states the statement may identify particular contraventions, practices, offences and persons.

Section 127(3) states
The senior administrator must not make a statement under this section unless satisfied—

(a) it is in the public interest to make the statement; and
(b) a public statement or warning has not been made, and is not about to be made, under another Act or process that is more appropriate in the circumstances.

In our view, it is the role of the Office of the Health Ombudsman (OHO) (recognising here s127(b) may permit this) to take action against offending health practitioners under existing processes, not the CE of QH. Blurring of regulatory roles only increases the risks of failures in natural justice.

Section 232 Making extended practice authorities

Section 232(1) reads -

The chief executive may make a document (an extended practice authority) -

The QNMU anticipates the chief executive may delegate this authority. In the case of nurses and midwives the extended practice authority (EPA) must be delegated to the Chief Nursing and Midwifery Officer (CNMO). We are already concerned about the QH governance structure and the inconsistent practices across Hospital and Health Services (HHS).

Current health practitioner regulation in Queensland reserves the right of RNs and midwives to determine the scope of nursing and midwifery practice, hence any EPA relevant to nursing and midwifery must be determined by the CNMO. The Nursing and Midwifery Board Australia (NMBA) regulates the practice of nursing and midwifery in Australia and one of its key roles is to protect the public. The NMBA does this by developing standards, codes and guidelines for nurses and midwives. In order to become registered, nurses and midwives must meet the NMBA's mandatory registration standards (NMBA, 2016a). Under this model of self-regulation, matters relating to EPAs in nursing and midwifery practice must be under the centralised authority of the CNMO.

We note section 138 of the regulation lists matters that must be considered for an EPA. Schedule 1 lists the EPAs, however, the table has a space for dates, so it is not clear whether

the regulation has to be updated every time an EPA is executed. If so, this would hinder any attempts to be responsive to changes in recommended use or availability of medicines.

Section 238 Delegation by chief executive

Amend S238 Delegation by chief executive to read -

The chief executive may delegate the chief executive's functions and powers under this Act, other than under section 127, to an appropriately qualified person who is a health service employee or public service employee **and has authority to direct the practice of a class of persons.**

Again, we are concerned each HHS may delegate nursing and midwifery functions and powers to persons who are not nurses or midwives. Under the national regulatory framework for health practitioners, RNs determine, coordinate and provide safe, quality nursing. This practice includes comprehensive assessment, development of a plan, implementation and evaluation of outcomes. As part of practice, RNs are responsible and accountable for supervision and the delegation of nursing activity to enrolled nurses (ENs) and others.

Practice is not restricted to the provision of direct clinical care. Nursing practice extends to any paid or unpaid role where the nurse uses their nursing skills and knowledge. This practice includes working in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory, policy development roles or other roles that impact on safe, effective delivery of services in the profession and/or use of the nurse's professional skills. RNs are responsible for autonomous practice within dynamic systems, and in relationships with other health care professionals (NMBA, 2016b).

Definitions

The term 'therapeutic use' is used in both the bill and regulation, yet there is no definition in either of these instruments. Section 12(2) of the bill notes - See the Poisons Standard, part 1 for the definition *therapeutic use*. Given this is a common term, we recommend the definition should be included in Schedule 1 - Dictionary.

There is no definition of Chief Executive in relation to the bill or regulation (there are several amendments to various other acts). The bill should make it clear this term refers only to the Chief Executive (Director-General) of the DoH (system manager) and not the Chief Executive of a HHS.

Medicines and Poisons Regulation 2019

Major Areas of Concern

Supervision

There are a number of sections within the regulation that indicate a clear misunderstanding of professional accountability. Current health practitioner regulation does not permit any health professional outside nursing and midwifery to *supervise* nurses and midwives. There is no hierarchy of medical practitioners who *supervise* NPs, nurses or midwives. NPs work autonomously.

We therefore seek an amendment to all references throughout the regulation and schedules that state a registered nurse or nurse practitioner is *under the supervision* of a registrar, specialist medical practitioner or medical practitioner to read *under the direction* of a registrar, specialist medical practitioner or medical practitioner. Only NPs, registered nurses and midwives are able to check the competency of other nurses and midwives. As a consequence we recommend the inclusion of the following definition of 'direction'-

Schedule 20 – Dictionary - insert a new definition of *direction* to read -

> ***Direction*** by a registrar, specialist medical practitioner or medical practitioner of a registered nurse or nurse practitioner means the oversight by the registrar, specialist medical practitioner or medical practitioner of the dealings of the registered nurse or nurse practitioner for directing, demonstrating and monitoring the dealings.

Section 24 – Administering under extended practice authority

In our view, the regulation should provide capacity for administering under an EPA for new and emerging nurse-led models of care particularly in areas where an RN or NP is the primary health professional. We recommend the inclusion of a new sub-section 24(3) to read -

24(3) A registered nurse may administer a medicine or give a treatment under a clinical protocol.

Examples –

1. **A registered nurse practising in the area of sexual assault.**
2. **A registered nurse practising in the area of forensic medicines.**

Section 27(1) Administering

Under current health practitioner regulation, only a RN is authorised to supervise an EN, not a medical practitioner. In an emergency situation where a medical practitioner seeks assistance from an EN to administer anaesthesia, whether in an operating theatre or a general practice, a RN competent in assisting with the administration of anaesthesia must be present to supervise the EN's performance of the procedure.

Including a provision such as clause 32(2) in the regulation validates and authorises unsafe practice and could ultimately exclude the RN from their rightful and mandatory role as supervisors of ENs. A RN or midwife would not supervise a health practitioner outside of nursing and midwifery. These lines of authority have been established for very sound reasons of accountability and safe practice. There can be no exceptions. If there are situations occurring that require administration of anaesthesia by an EN with no RN available, then the facility must change its procedures, not seek to circumvent the regulation of the nursing profession to accommodate unsafe practice.

We recommend the wording now read -

> An enrolled nurse **supervised by a registered nurse** may administer a medicine to a patient under the direct ~~*supervision*~~ **observation** of a medical practitioner administering anaesthesia if it is reasonably necessary to ensure the safety of the patient before, or during, the patient's anaesthetic procedure.

Section 38 Oral or informal prescribing

This section needs more clarification as to whether other forms of administration such as intravenous are included.

(4) If the prescriber gives an informal prescription, it may be given only to a person who is authorised to administer the medicine.

As the Medicines Regulation and Quality unit is aware, interpretation of the current HDPR has resulted in various pieces of legal advice regarding whether a prescriber gives an oral instruction to administer a medicine to an individual or to a class of persons. Section 38(4) above should include a note explaining whether the order applies to all of the persons authorised or only persons to whom the prescription is given.

(5) The written prescription must be given, or the signature made, as soon as practicable but no later than the next business day after the medicine was administered.

Section 38(5) above should outline the procedures to follow if the written prescription is not given nor the signature made by the next business day.

Section 110 Review – Act s.93

(2) For section 93(3) (b) of the Act, a substance management plan must be reviewed –

This section does not state who will be carrying out the review or possible outcomes from a review.

Schedule 7 Part 1 - 1 Definitions for schedule

This schedule needs to include an additional definition for *Enrolled Nurses with Notation* in accordance with the requirements of the regulator, the Nursing and Midwifery Board of Australia (NMBA).

ENs who **can** administer medicines **do not have a notation** on their registration. This means they have successfully completed EN medication administration education. This education may have been completed before or after the introduction of the National Registration and Accreditation Scheme.

ENs who **cannot** administer medicines **have the notation *'does not hold board-approved qualification in administration of medicines'*** on their registration, which is available on the national register of practitioners.

The NMBA Fact Sheet (2018) on *Enrolled Nurses and medicine administration* clearly states 'ENs *with* a notation cannot administer medicines'. Thus, the regulation enables ENs with a notation to engage in unprofessional conduct.

ENs with a condition on their registration limiting their practice to mothercraft nursing only are also unable to administer medicines.

It is expected all ENs who do not have a notation have successfully completed EN medication administration education and have the competence and confidence to administer medications safely, regardless of when the initial education occurred (NMBA, 2018).

We recommend Schedule 7 Part 1 – 1 Definitions for schedule be amended to include –

> ***Enrolled Nurse*** **means an Enrolled Nurse who does not have a notation in respect to medicine administration on their registration.**

Schedule 20 – dictionary

Amend the definition of ***clinical protocol*** as per our recommendation under section 24 to read -

> ***clinical protocol*** means a standing order applying in relation to an approved person performing a procedure or diagnostic test for practising any of the following professions—
> (a) clinical perfusion;
> (b) nuclear medicine technology;
> (c) respiratory science;
> (d) speech pathology;
> **(e) registered nurse**

Insert a new definition of ***direction*** to read -

> ***direction*** by a registrar, specialist medical practitioner or medical practitioner of a registered nurse or nurse practitioner means the oversight by the registrar, specialist medical practitioner or medical practitioner of the dealings of the registered nurse or nurse practitioner for directing, demonstrating and monitoring the dealings.

Aged Care

The note to Schedule 13 of the regulation poses a number of concerns for the QNMU including:

- the re-introduction of an aged care worker into the regulatory framework;
- the replacement of nurses by AINs/PCWs which will result;
- the capacity of the person responsible for the entity's SMP (e.g. an aged care provider) to determine competency requirements, and training and supervision of staff (presumably including unregulated care workers in relation to medicines);
- the lack of work value assessment and proper industrial process for introducing a new category of worker.

Aged Care Worker

Schedule 13 – Institutions and facilities – Aged care facilities – of the regulation opens the possibility to reintroduce the aged care worker into the new regime.

Based on the previous draft regulation released in September, 2018, an aged care worker will be able to administer many routine medicines under the poorly-defined supervision of the RN. The supervising RN must determine the aged care worker is capable and competent to perform an activity safely. The *Decision-Making Framework for the RN* (NMBA, 2013) supports the delegation of care to support workers, however the regulation fails to recognise the RN has to meet seven criteria before delegating including that the delegation is consistent with professional nursing standards. Under the previously proposed legislation, the aged care worker may administer:

- a medicine dispensed and packaged by a pharmacist into a DAA labelled for administration to the resident;
- an S2, S3, or S4 medicine that has been dispensed or lawfully supplied to the resident;
- another S2, S3 or S4 medicine that has been dispensed or lawfully supplied to the resident.

We note here many of the medicines used in aged care are listed in the bill as 'high risk'. We also note many aged care workers are from culturally and linguistically diverse backgrounds and are not examined with regard to their English language literacy or numeracy to the level required by nurses administering medicines. Further, unregulated aged care workers have little if any knowledge of ageing anatomy and physiology and no knowledge of pharmacology, pharmacokinetics and pharmacodynamics.

Residential aged care facilities, while not hospitals, are places where considerable and often complex health care takes place to an increasingly ageing, frail cohort with a significant and rising morbidity profile. Due to the decreasing length of stay in residential aged care and the increasing intensity of care, these facilities are more like hospices or subacute, non-acute care facilities rather than the more traditional perception of a nursing home.

The ACSQHC has identified medication management as a significant patient safety concern. There is a separate medication safety health service accreditation standard (Standard 4) which clearly identifies medication management as a patient safety risk area of practice. The same classes of high-risk drugs used in the hospital sector are also widely prescribed and administered in the aged care sector. The APINCHS[2] classification of high-risk medicines comprises the following classes of drugs:

- **A**ntimicrobials;
- **P**otassium and other electrolytes;
- **I**nsulin;
- **N**arcotics (opioids) and other sedatives;
- **C**hemotherapeutic agents;
- **H**eparin and other anti-coagulants;
- **S**ystems (ACSQHC, 2018).

The Commonwealth Department of Health's *Guiding Principles for Medication Management in Residential Aged Care Facilities* (2012) also clearly identifies insulin as a high-risk medication used in residential aged care along with anticoagulants, chemotherapy agents, narcotics and sedatives. Given the risks associated with administration of insulin to frail elderly, and the knowledge necessary to manage insulin dependent diabetes effectively, unregulated carers clearly have no role to play in this regard.

Importantly, it is the inherent risk to safe practice that comes with dividing or decentralising critical tasks, such as medication management and administration, which increases the risk of system failure and harmful events occurring. The impact of these 'human factors' on safe practice are well recognised, and it is concerning that this legislation and regulation should not consider these issues in relation to medication management in the aged care sector.

This also applies to the potential for an aged care worker to administer a medicine dispensed and packaged by a pharmacist into a DAA labelled for administration to the resident. In our experience, pharmacy assistants, not necessarily a pharmacist may package medicines into DAAs. This is an important area of clarification given research indicating errors in packaging

[2] The acronym **APINCHS** is designed to serve as a reminder that even routinely administered medicines pose a high risk to patient safety.

DAAs at around 12% (Australian Nursing Federation, 2012). We discuss this further under the section on 'Aged Care'.

The addition of an aged care worker into the medication administration process would increase the complexity of the system and thus safety risks, increase opportunities for miscommunication and move RNs to a supervisory role, thus decreasing their capacity to detect and intervene to prevent medication related errors. In medication management, supervision is no substitute for RNs and ENs undertaking this task directly. Nor can unregulated care workers be expected to have the same error detection skills as nurses, again increasing the risk the errors will not be 'caught'.

The Private Sector

We see there is potential for providers in the private sector to view the role of the aged care worker in the aged care sector as a legitimate reason to employ non-regulated workers in a similar capacity in private health services as a result of the precedent this legislation may set. We experienced this phenomenon in 1996 when the current HDPR incorporated the 'carer provisions'. Aged care providers were very quick to investigate the potential for their unregulated workers to administer medicines in both high and low care settings. This resulted in 10 years of protracted negotiations with QH and stakeholders before QH eventually abandoned draft guidelines due to the risks to residents' health.

We see no impediment for that debacle to be repeated with private sector health services that employ AINs by changing their titles to those that may be captured by the current wording of agents and carers in section 51 of the regulation.

An Entity's SMP

An entity's SMP would allow for the provider to determine competency requirements, training and supervision of staff. A current issue in aged care is provider developed medication 'assistance' competency training that is often very brief and inadequate for the administration of medicine. Even current VET training related to medication assistance such as *HLTHPS006 Assist clients with medication*, as part of a Certificate III or IV course such as ageing support only equip unregulated care workers to assist competent residents with self-administration of medications, compared to the extensive pharmacological knowledge and training of an undergraduate nursing degree. An example of the HLTHPS006 course content is identified below (ALACC Health College Australia, 2018):

- Theory: 3 Hours;
- Skills Training: 3 Hours;

- Assessment (comprising self-directed study): 14 Hours;
- Assessment Assistance: 10 Hours;
- Practical Placement Experience: 50 Hours.

This relatively scant training does not compare to the hundreds of hours of training (theory and practice) in medication management undertaken by nursing undergraduates.

In relation to DAAs, our peak body, the Australian Nursing and Midwifery Federation Policy (2015) states -

> *Health workers other than registered nurses, midwives and enrolled nurses may provide physical assistance to an individual who is self-administering their medicine, at the individual's request provided the individual has been assessed as being able to self-administer.*

Research suggests error rates for DAAs in residential aged care exceed 12% and can be as high as 21% (Pharmaceutical Society of Australia Ltd, 2019, p.15; Australian Nursing Federation, 2012). This is a significant hazard as aged care workers will be unable to identify an incorrect pill(s) or tablet(s) in a DAA.

Given the potential risk associated with all medication errors, it is unlikely minimally trained, unregulated care workers have the knowledge or skills necessary to 'catch' these errors prior to administration, detect errors of administration, nor respond appropriately to the consequences of such errors should they occur.

Medication management consists of more than administering medications. It involves assessment of the resident, administration of the prescribed medication and follow up in relation to therapeutic effects, side effects and adverse reactions. The capacity of RNs and ENs to detect and respond to medication errors and adverse events is highly dependent on them being the person who administers the medication. Unregulated care workers simply do not have the theoretical knowledge base and skills to undertake this role.

These concerns relate specifically to aged care workers employed in that capacity and are not intended to impact on family members or significant others who care for older Australians. Any changes to the regulation to introduce an aged care worker will work towards providing a lesser standard of care for aged care residents than other members of the public. For example, if an aged care resident taking morphine were to fall and injure themselves at an aged care facility such that they were admitted to hospital, at least one RN, quite possibly two, would check and administer the drug during their stay. On return to the aged care facility, an AIN could administer the drug through a DAA with no checking or assessment of the resident.

In our view, any provisions relating to aged care workers must be consistent with medication management practice standards and guiding principles that are published or supported by the Commonwealth Department of Health (2018). These standards and guiding principles were developed by the National Medicines Policy Unit. They state (p. 60), through the resources provided to RNs, the aged care worker may assist the aged care resident with their medicines only if the resident has been assessed as competent to self-administer, but needs help to access or administer the medication.

Hence, any provisions in the regulation relevant to aged care workers must be consistent with national guidelines and best practice standards in the administering of medicines, otherwise the legislature could be negligent in its duty to ensure the statute protects the public from harm.

Work Value

There are industrial ramifications associated with introducing the aged care worker into the nursing workforce. Industrial instruments in the aged care sector currently refer to AIN/PCWs. We have attached a model enterprise agreement clause which is supported by both the QNMU and United Voice that clearly sets out the procedure and circumstances under which an AIN/PCW may assist with medication.

Wages and other employment conditions for the vast majority of AINS/PCWs in Queensland are set by enterprise agreements. They have been made in the context of the current HDPR which quite properly prevents AINs/PCWs from administering medicine. If the regulation reintroduces aged care workers, the position of AINS/PCWs in Queensland will be adversely affected, particularly in light of a very relevant and recent Fair Work Commission (FWC) decision relating to some NSW PCWs.[3]

The regulation is not the vehicle by which the DoH should seek to introduce a new classification of worker that has not been the subject of a work value assessment or the result of any form of consultation with nurses and their union. Enterprise bargaining or other industrial consultation mechanisms are the proper forum for any discussion around new classification levels for nursing staff.

Both professionally and industrially, the QNMU objects strongly to including the aged care worker in the regulation.

[3] Here, The FWC found a nursing home's agreement allows it to make carers responsible for insulin injections when nurses are unavailable, despite the fears, protestations and lack of extra pay for these workers, but only if the employer improves training practices. See *Health Services Union – New South Wales Branch v Gulgong Hostel Association Inc (t/a Wenonah Lodge & Wenonah Community Care)* [2018] FWC 4925 (23 August 2018).

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Attachment A

Medication

1. An AIN/PCW may assist a resident/client with their medication, if, and only if:
    a. The resident/client's clinical record or care plan records an assessment by a medical practitioner, Registered nurse or pharmacist that the resident/client has the capacity to self-administer their medications;
    b. The resident/client is mentally competent to request assistance and personally requests that assistance.
    c. The AIN/PCW has:
        i. has completed the training module "Assist Clients with medication" HLTHPS006 (or if it is replaced, its replacement) of a Certificate III course in aged care, and;
        ii. has been deemed competent to undertake the particular medication assistance, and delegated to provide that assistance, by the Registered nurse on duty responsible for the resident/client care plan , and;
        iii. is fully supervised by the Registered nurse when providing medication assistance.
    d. Employer instructions to employees relating to medications are consistent with relevant statutes and regulations, e.g. *Health (Drugs and Poisons) Regulation 1996* (Qld)*, Health Practitioner Regulation National Law Act 2009* (Qld), *Fair Work Act 2009.*

2. The employer must pay an AIN/PCW who has completed the module "Assist Clients with medication" an allowance per hour equal to the difference between the base rate to which the AIN/PCW is entitled and the base rate that the employee would be entitled to if she/he was an Enrolled Nurse.

3. The Registered nurse has overall responsibility for medication management in line with legislation and professional standards.

4. The role of the Registered nurse, and enrolled nurse who works under the direction and supervision of a Registered nurse, in medication management includes the following:
    a. administration of medicines;
    b. supervision of individuals who are self-administering medicines;
    c. recording of any medicines administered, withheld or refused;

d. compliance with legislative requirements and organisational policies and protocols, in particular, medicine incidents and error recording and reporting requirements;
e. a knowledge of pharmacokinetics, pharmacodynamics and pharmacogenetics, as well as polypharmacy issues for residents/clients
f. assessment of the health status of the resident/client and exercising decision making skills and professional judgement in relation to medicines use, including knowing why to administer, how to administer, when to administer, when not to administer, and when to report or refer to a medical practitioner, other prescribing practitioner, such as a nurse practitioner, or a pharmacist;
g. coordination, implementation, supervision, ongoing monitoring and evaluation of safe medicines administration practices;
h. monitoring and evaluation of medicines use, including reporting and recording of reactions to medicines and the initiation of required interventions in consultation with medical practitioners or other prescribing practitioners, and pharmacists.

5. "Administer medication" means "*to give a person a single treatment dose of a drug to be taken by the person immediately"* by any means including by swallowing, applying, inhaling or injecting. It requires specialised knowledge and clinical reasoning to:
   - confirm resident identify and check allergies and interactions (right person check)
   - confirm the correct medication (right medication check)
   - confirm appropriate dose (right dose check)
   - confirm appropriate route (right route check)
   - check frequency of medication and when last given (right time check)
   - confirm rationale for drug – may no longer be required if a short course
   - check that the drug had the desired effect or other effects that need to be monitored or escalated
   - document administration (right documentation check)

   AINs/PCWs are not authorised to administer drugs.

6. "Medication assistance" means:
   - reminding and/or prompting a resident/client to take the medication
   - assisting (if needed) with opening of medication containers for the client/resident at his/her request and direction

- bringing packs of medicines to a person at their request so that the person can take the medicines
- reading labels aloud to the client/resident and advising the time (e.g. “3pm”) at the request of the person who is going to take the medicine
- ensuring the resident/client has a drink to take with his or her medication.

Any term of this clause prevails over any other term of this agreement to the extent of any inconsistency.