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ORIGINAL RESEARCH

A bitter pill to swallow: registered nurses and medicines regulation in remote Australia

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ABSTRACT:

Introduction: Access to essential medicines is a human right and an objective of the National Medicines Policy in Australia. Health workforce distribution characteristics in remote Australia implies registered nurses (RNs) may find themselves responsible for a broader range of activities in the medication management cycle than they would be elsewhere in the nation. The regulation of health professionals and their training requirements provides essential but complex protections for the public. These protections include the National Registration and Accreditation Scheme for health practitioners and the Australian Health Practitioner Regulation Agency. Other levels of control or regulation are also exerted over health professionals via mechanisms such as salaries and funding arrangements, insurance requirements, admitting rights to healthcare facilities,

and legislation controlling the use of medicines and therapeutic devices. This study aimed to examine national legislation and regulations concerning the use of medications from a nursing perspective, focusing on the context of health service delivery in remote areas.

Methods: Australian state and territory medicines legislation and regulations was interrogated for answers to the questions 'Can an RN prescribe a medication?', 'Can an RN dispense a medication?', 'Can an RN supply or issue a medication?' and 'Can an RN administer a medication?'

Results: Inconsistencies were identified nationally in the names and general structure of the legislation, the location of information relating to authorised roles with regards to medications and key terms used to describe medicines and the

elements of the medication management cycle. Administrations of Schedule 4 and 8 medicine according to an order from an authorised prescriber are the only nationally consistent roles RNs are authorised to undertake with regards to medicines. Twenty-eight variations were identified with regards to additional authorisations for RNs.

Conclusion: RNs make up more than half of the registered Australian health professional workforce and are the most consistently distributed across the nation, yet their legislated responsibilities in relation to working with medicines are inconsistent. Given the inconsistencies, RNs providing health care in remote Australia may be unable to undertake aspects of

the medication management cycle that their work environment demands in the best interest of their patients and absence of other healthcare providers. The lack of legislative consistency nationally for medicines in Australia is likely to impede timely access to medications for patients. Regulatory inconsistencies may also result in RNs working well below or beyond their legal scope of practice, thereby creating clinical and workforce risks. Such risks are a significant matter for remote health service provision. Resolving these issues will require a collaborative national approach with consideration given to how the health workforce is distributed, current nursing responsibilities and relevant service delivery models for remote Australia.

Keywords:

access, Australia, equity, health, legislation, medicines, nursing, regulation.

FULL ARTICLE:

Introduction

The regulation of health professionals and their training requirements provides essential but complex protections for the public¹. In Australia, these protections include the introduction of a National Registration and Accreditation Scheme for health practitioners (NRAS) in 2010 and the establishment of the Australian Health Practitioner Regulation Agency (AHPRA)². Other levels of control or regulation are also exerted over health professionals via mechanisms such as salaries and funding arrangements, insurance requirements, admitting rights to healthcare facilities, and legislation controlling the use of medicines and therapeutic devices^{2,3}.

Access to essential medicines is a human right in the International Treaty on Social, Economic and Cultural Rights⁴. Its importance is also evidenced in the Declaration of Alma Ata⁵ and the Sustainable Development Goals⁶. Australia is a signatory to each of these instruments, and appropriate and timely access to medicine is also a central objective of Australia's National Medicines Policy⁷. Australia's Pharmaceutical Benefits Scheme (PBS) underpins affordable access to essential medicines. In 2016–2017, approximately 0.7% of the nation's gross domestic product (A\$12.06 billion) was spent on medicines subsidised through the PBS⁸, reflecting their critical, varied role.

In Australia, when episodes of health care involve the use of medicines it is acknowledged that the Medication Management Cycle (MMC) will occur^{9,10}. The MMC has been described as consisting of nine steps^{9,10}:

1. deciding to prescribe a medicine
2. recording the medication order or prescription
3. reviewing the medication order/prescription
4. issuing the medicines, which includes manufacturing and dispensing or supplying the medicine
5. providing medicines information to the consumer and those involved in storing and administering the medicine
6. appropriately distributing and storing the medicine
7. administering the medicine
8. monitoring the consumers' response to the medicine

9. communicating or transferring verified information regarding medicines use and treatment plans.

While many healthcare professionals may be involved in different phases of the MMC, in Australia, medical practitioners and pharmacists are generally acknowledged as responsible for the first six. Nevertheless, because medications play such a vital role in health care and because other professionals, including nurses, are also expected to play at least some role in the MMC, instruments that provide a means of effecting control and coordination of use must have demonstrable relevance.

Among such instruments, legislation is key to clarifying where, by whom and how acts of prescribing, dispensing, supplying and administering medications should occur. Within Australia's busy, federated legislative landscape, there are many opportunities for incongruence between instruments that pertain to medicines. Although this has been identified as a risk to patients and health professionals^{11–15}, little has been published about the issue with regard to registered nurses (RNs) and no complete analysis has been undertaken from a nursing perspective since the introduction of the NRAS and AHPRA in 2010 and subsequent changes to medicines legislation^{14,16}.

This is a significant gap because RNs and RN/midwives are the mainstay of the Australian health professional workforce, comprising more than half of its total (53.6% in 2017) and are the most evenly distributed across the nation^{17–19} (Fig1). Moreover, in the remote and very remote areas that constitute most of Australia's land mass and where community health and wellbeing are generally poorest²⁰, the role of RNs is especially significant, with many communities reliant on nurse-led services^{21,22}. In these parts of the nation, RNs have historically been and continue to be the mainstay and therefore tend to carry more responsibility for healthcare delivery, including the MMC^{21–23}.

The nurse practitioner (NP) role has been recognised in Australia since 2000. In Australia, NPs are RNs who have completed postgraduate training at a masters level and have applied for and hold the specific NMBA Nurse Practitioner endorsement. NPs are authorised prescribers within their individual speciality areas and are able to apply for Pharmaceutical Benefits Scheme (PBS) prescribing rights²⁴. Despite initial hopes that NPs would fill the medical practitioner void in remote Australia, Figure 1 highlights that this has not been the case to date. Indeed, according to

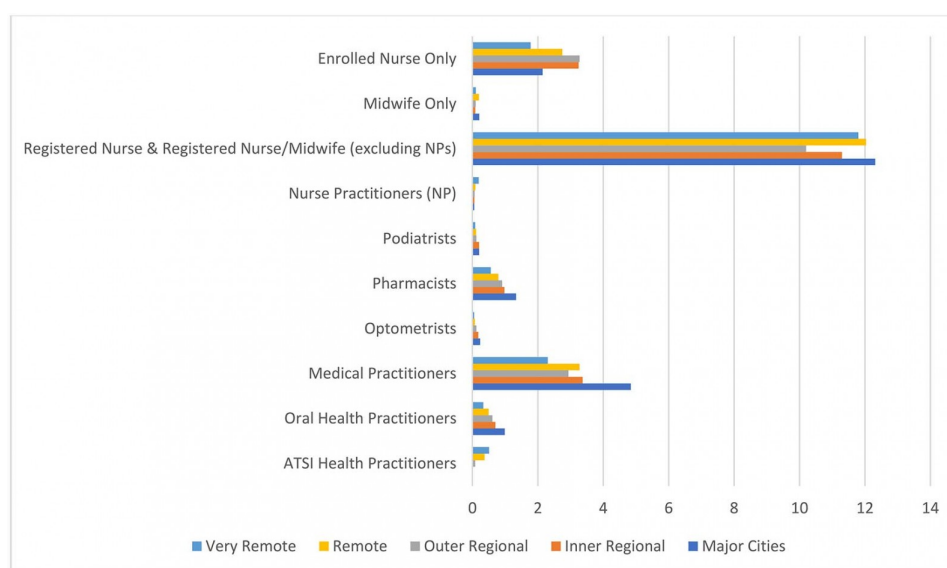
2017 health workforce figures an additional 481 NPs would be required in very remote Australia to bring the combined medical practitioner-to-NP ratio in line with that of major cities¹⁷⁻¹⁹.

The extended role of nurses in medication management in remote Australia has been acknowledged from the earliest days of the PBS²⁵. In 1999, amendments made to the *National Health Act 1953* effectively established the Remote Area Aboriginal Health Service program, enabling the free supply of PBS medications without a prescription at designated facilities in remote areas²⁶. This removed a barrier to accessing affordable medicines due to a lack of local medical practitioners for obtaining prescriptions and pharmacies for the dispensing of medications. Despite this, it is unclear if nurses in these areas, whose roles have in common some elements of work usually undertaken by general practitioners or pharmacists²¹ and may

therefore include supplying and/or initiating medications, are also supported to do this by state or territory legislation governing the practices of health practitioners with regards to medicines.

Despite the significance of these advanced practice roles for RNs and the crucial position they therefore hold in the quality use of medicines there has, been little research outside of Queensland into RNs and the MMC in remote Australia or the legislative and practice frameworks that might best support quality use of medicines by nurses in remote Australia.

The objective of this study was to examine medicines and poisons legislation nationally from a nursing perspective, with a focus on the context of health service delivery in remote areas of Australia.



Source: References 18–20.
ATSI, Aboriginal or Torres Strait Islander.

Figure 1: 2017 health professional by type per 1000 estimated resident population and Australian Statistical Geography Standard – Remoteness Area 2016.

Methods

In August 2017, state and territory medicines legislation and regulations for all Australian states and territories that have areas classed as ‘very remote’ according to the Australian Statistical Geography Standard – Remoteness Area 2016 (ASGS–RA 2016)²⁷ were interrogated for answers to the questions ‘Can an RN prescribe a medication?’, ‘Can an RN dispense a medication?’, ‘Can an RN supply or issue a medication?’ and ‘Can an RN administer a medication?’ in regards to RNs who do not hold NP endorsement. The legislation was again reviewed in 2019 for changes and amendments; at this time Victoria and the Australian Capital Territory were included in analysis for National completeness (Supplementary table 1). The medicines and poisons, or similarly titled Act and Regulations for each state and territory, will hereafter be referred to by abbreviated state or territory name and ‘Act’ or ‘Regulation’.

Findings will be presented as descriptions of the relevant definitions, authorisations and sections of legislation accessed in order to answer the identified questions for Schedule 2, 3, 4 and 8 medicines. Tables will be used where possible to summarise

findings.

Supplementary table 1: Overview of Australian state and territory medicines legislation and regulations

Ethics approval

Ethics approval was granted from the Edith Cowan University Human Research Ethics Committee (Approval 19386).

Results

Instrument and format

The title of legal instruments and location of legislative details regarding authorisations for RNs regarding medicines varies across Australian states and territories. In South Australia (SA), the Northern Territory (NT) and New South Wales (NSW) most of these details are contained within the relevant Act. In Queensland, the Australian Capital Territory (ACT), Victoria, Tasmania and Western Australia (WA), the details are predominantly located within Regulations.

In addition to Acts and Regulations, other regulatory processes

such as gazetting or the issuing of individual authorisations or licences are enabled in legislation and utilised variably across the nation.

Scheduling of medicines

All Australian states and territories are party to a federal legislative instrument, the Poisons Standard (2019), also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The terminology used to describe and refer to the different schedules of medicine within both state and territory legislation differs from the SUSMP (Table 1).

Table 1: Standard for the Uniform Scheduling of Medicines and Poisons definition and terminology used to describe medicine schedules in Australian legislation

| State | Schedule 2 | Schedule 3 | Schedule 4 | Schedule 8 |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SUSMP | Pharmacy Medicine Substance for which safe use may require advice from a pharmacist and that should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person | Pharmacist Only Medicine Substance for which safe use requires professional advice but that should be available to the public from a pharmacist without a prescription | Prescription Only Medicine, or Prescription Animal Remedy – Substance for which use or supply should be by or on the order of persons permitted by state or territory legislation to prescribe and should be available from a pharmacist on prescription | Controlled Drug – Substance that should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence |
| SA | Poison | Poison | Poison, S4 drug, prescription drug | Poison, prescription drug, drug of dependence |
| WA | Poison, S2 | Poison, S3 | Poison, S4, S4 reportable poison, drug of addiction | Poison, S8, drug of addiction |
| NT | S2 | S3 | Restricted S4 substance, unrestricted S4 substance | Restricted S8 substance, unrestricted S8 substance |
| Qld | Regulated substance, S2 medicine | Regulated substance, S3 medicine | Regulated substance, S4 medicine, restricted drug | Regulated substance, S8 medicine, controlled drug |
| NSW | Poison | Poison | Poison, restricted substance | Drug of addiction |
| ACT | Non-prescription medicine, medicine, pharmacy medicine, declared substance, regulated substance | Non-prescription medicine, medicine, pharmacist only medicine, declared substance, regulated substance | Prescription medicine, medicine, declared substance, regulated substance | Controlled medicine, medicine, declared substance, reportable substance, regulated substance |
| Vic | Poison, controlled substance, S2 poison | Poison, controlled substance, S3 poison | Poison, controlled substance, S4 poison | Poison, controlled substance, drug of dependence, S8 poison |
| Tas | Medicinal poison, poison, Scheduled substance | Poison, potent substance, Scheduled substance | Restricted substance, Scheduled substance | Drug of dependence, narcotic substance, Scheduled substance |

ACT, Australian Capital Territory. NSW, New South Wales. NT, Northern Territory. Qld, Queensland. SA, South Australia. SUSMP, Standard for the Uniform Scheduling of Medicines and Poisons. Tas, Tasmania. WA, Western Australia.

Endorsements, training, authorities and protocols

A variety of mechanisms across Australia make provisions for RNs to work more broadly through the MMC. The *National Health Practitioner Law Act 2010*, as enacted by each state and territory and enabling the powers and responsibilities of NRAS and AHPRA, makes provision for suitably qualified, registered health professionals to apply for an endorsement in a certain area of practice²⁸. RNs who have undertaken approved training can apply to the Nursing and Midwifery Board of Australia (NMBA) for an endorsement for scheduled medicines for RNs (rural and isolated practice) (Registration Standard for Endorsement of Registered Nurses (Rural and Isolated Practice) –RIPEN)²⁹. This endorsement is recognised in legislation in all states and territories with the exception of WA and Tasmania²⁹. However, Queensland and Victoria are the only states in which RIPEN is actually needed for an RN to undertake broader aspects of medication management practice. The NMBA is preparing to discontinue RIPEN²⁹.

In NSW, a letter of appointment may allow RNs to supply and/or initiate listed medications according to Standing Orders for the Supply or Administration of Medications under the Nurse Designated Emergency Care (NDEC) model and related

Guidelines and Medication Standing Orders³⁰. This entails training and certification that is only available and recognised in a limited number of NSW rural and remote facilities. In WA, RNs providing sexual health services are required to undertake additional training to be able to initiate medications according to specific protocols. There is no requirement in WA for RNs in remote nursing roles to undertake additional education prior to initiating and supplying medications according to remote area nursing protocols³¹. Similarly, in SA, the NT, ACT and Tasmania, there are no requirements for RNs to have undertaken additional education to supply medications according to a protocol.

Definitions and the terminology describing protocols and standing orders also vary across the country, and different protocols are authorised through state or territory legislation to allow RNs to undertake extended MMC roles. Both Queensland and Victoria utilise the Primary Clinical Care Manuals (PCCM) for most nurse-managed care for acute presentations in remote contexts. In the NT and at multiple remote health sites in SA³² the Remote Primary Healthcare Manual (RPHCM) suite has been adopted. The NDEC Nursing Management Guidelines (NDEC NMG) and Medication Standing Orders are utilised at limited sites in NSW³⁰. The PCCM, RPHCM and NDEC NMG provide guidance on the assessment and management for common

presentations and protocols for the use of specific drugs. South Australian and Tasmanian legislative mechanisms do not stipulate the use of specific manuals or protocols. WA utilises a system of Structured Administration and Supply Arrangements (SASAs) to authorise administration and supply of medications by RNs in certain contexts. A variety of SASAs are issued by the state, and mechanisms exist for health organisations or individual medical practitioners to develop their own SASAs for use by RNs³¹. Unlike the RPHCM, PCCM and NDEC NMG, SASAs only relate to a specific medication, its indication for use and dose. SASAs do not provide guidance for RNs around patient assessment, differential diagnoses or clinical decision-making guidance in respect to the condition being treated. Endorsements and training requirements relating to RNs who are immunisation providers were not included in this analysis due to their multitude and complexity.

Prescribe, prescriber, prescription

Prescribing traditionally relates to stages 1–3 of the MMC.

Definition: Definitions of terms, where provided, are in the Act for WA, the NT and Queensland. SA defines only *prescriber* in the Regulations. The ACT defines *prescribe* and *prescription* in the Act and *prescriber* in the Regulations. No clear definitions are provided by NSW or Tasmania. Victoria defines *prescription* by listing two provisions of what a prescription is not within the Regulations (Table 2).

Authorised actions for RNs: RNs without an NP's endorsement are not authorised to prescribe medications in any practice context. However, under the new Queensland *Medicines and Poisons Act 2019*, there are provisions for individuals to apply for a prescribing approval, and this could include RNs.

Table 2: Definitions and authorised actions for *prescribe* and *dispense*

| State | Source | Definitions of <i>prescribe</i> , <i>prescriber</i> , <i>prescription</i> | Can an RN prescribe a medication? | Definition of <i>dispense</i> | Can an RN dispense a medication? |
|-------|----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| SA | Regulations 2011 s3, s35 | <i>Prescriber</i> means a person who lawfully gives a prescription for a drug | No | <i>Dispense</i> means to supply a drug in accordance with a prescription for that drug | Unclear |
| WA | Act 2014 s7; Regulations s3, s23, s54 | <p><i>Prescribe</i>, in relation to a poison, means to issue a prescription for the poison</p> <p><i>Prescriber</i>, in relation to a Schedule 4 or 8 poison, means an authorised health professional who has authority to prescribe the poison</p> <p><i>Prescription</i>, in relation to a Schedule 4 or 8 poison, means a document (whether written or electronic) that – (a) sets out particulars of the poison, or a substance that contains the poison, that is, for therapeutic purposes, to be – (i) used by, or administered to, a person named in the document; or (ii) administered to an animal described in the document; and (b) is issued for the purpose of enabling the poison to be supplied for that purpose; and (c) complies with any requirements prescribed by the regulations</p> | No | <i>Dispense</i> means to supply in accordance with a prescription | No |
| NT | Act 2012 s5, s19 | <p><i>Authorised prescriber</i>, for a Scheduled substance, means a health practitioner or veterinarian who is authorised under part 2.4, division 1, to issue a prescription for the supply of the substance</p> <p><i>Prescription</i>, for a Scheduled substance, is a written instruction authorising the supply of the substance for: (a) administering to a particular person; or (b) administering to animals</p> | No | Not defined | Unclear |
| Qld | Act 2019 s25(2); Regulation 1996 s64, s67, s68, Appendix 9 p296 | <p><i>Prescribe</i>, in relation to a medicine, means direct a person, orally or in writing, to administer, dispense or give a treatment dose of the medicine for the treatment of a person or animal</p> <p><i>Prescription</i>, in relation to a medicine, means a direction, orally or in writing, to administer, dispense or give a treatment dose of the medicine for the treatment of a person or animal</p> <p><i>Prescribing approval</i> is an approval that authorises a person to carry out any of the following regulated activities with a medicine stated in the approval – (a) prescribing the medicine for a person, or a class of persons, stated in the approval in the stated circumstances; (b) buying, possessing, administering, dispensing and giving a treatment dose of the medicine in the stated circumstances</p> | Potentially | <p><i>Dispense</i> a medicine, means sell the medicine to a person on prescription</p> <p><i>Dispense</i> means sell on prescription</p> | No |
| NSW | Act 1966 s4, s36aa; Regulation 2008, s128b p56 | <i>Prescribe</i> and issue a prescription includes make an entry on a patient's medication chart for treatment of the patient | No | Not defined, see definition of <i>supply</i> | No |
| ACT | Act 2008 s24, s120, dictionary p166; Regulation 2008, s123(3) pp35–6 | <p><i>Prescribe</i> a medicine means issue a prescription for the medicine</p> <p><i>Prescription</i>, in relation to a medicine, means an oral or written direction (other than a purchase order, requisition or standing order) to a person – (a) who is authorised to administer the medicine to administer the medicine; or (b) who is authorised to dispense the medicine to dispense the medicine</p> <p><i>Authorised prescriber</i>, in relation to a prescription, means – for a medicine other than a controlled medicine – a person who is authorised to issue the prescription under the act or another territory law; and (b) for a controlled medicine – a person who is authorised to issue the prescription under part 13.1 (controlled medicines approvals)</p> | No | <i>Dispense</i> means supply on prescription | No |
| Vic | Regulations 2017 s5, s39, s142 | <i>Prescription</i> does not include – (a) a chart instruction; or (b) an authorisation under part 8 of chapter 2 | No | Not defined | Unclear |
| Tas | Act 1971 s3; Regulations 2018 s23 | Not defined | No | Not defined, see definition of <i>supply</i> | Unclear |

ACT, Australian Capital Territory. NSW, New South Wales. NT, Northern Territory. Qld, Queensland. RN, registered nurse. SA, South Australia. Tas, Tasmania. WA, Western Australia.

Dispense

The dispensing of medications traditionally involves stages 4–6 of the MMC.

Definition: The ACT defines *dispense* in the Act, and SA and WA within the Regulations similarly as being to supply a drug according to a prescription. Queensland also defines the term within its Regulations but specifies that dispensing is to sell a drug in accordance with a prescription. The NT makes no reference to the term. Victoria does not define the term. NSW and Tasmania do not define the term but in these states *supply* includes the act of dispensing, with Tasmania specifying that dispensing occurs in accordance with a prescription (Table 3).

Authorised actions for RNs: SA only mentions pharmacists and medical practitioners in the more than 12 provisions for actions that must be undertaken when dispensing. RNs in WA and Queensland are not authorised to dispense. Dispensing is not a specific action regulated in the NT. Pharmacists are the only health professionals authorised to dispense in NSW. The situation in Tasmania is unclear because *person* is undefined when referring to the dispensing of narcotic substances and RNs' status related to dispensing is not clarified. *Dispense* is not defined by Victoria; however, authorised (RIPEN) RNs may sell Schedule 3, 4 and 8 medications to patients under their care if there is a therapeutic need; there is no stipulation that a prescription is required.

Table 3: Definitions and authorised actions for *supply*

| State | Source | Definition of <i>supply</i> | Can an RN supply a medication? | | | |
|-------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| | | | Schedule 2 | Schedule 3 | Schedule 4 | Schedule 8 |
| SA | Act 1984 p11, s15(1a), s18(1c) | <i>Supply</i> means provide or distribute or offer to provide or distribute | Yes | Yes | Yes ^a | Yes ^a |
| WA | Act 2014 s8, s13(2); Regulations 2016 s16A, s54 | <i>Supply</i> , in relation to a poison, means to supply the poison, or a substance that contains the poison, to another person, but does not include administering a poison or substance directly to another person or to an animal. (2) For the purposes of this Act a person is taken to supply a poison if the person does any of the following – (a) agrees to supply the poison; (b) makes available, advertises, displays with a view to supplying, or otherwise offers to supply, the poison; (c) has possession of the poison for the purpose of supplying it | Yes ^{b&c} Yes ^d | Yes ^{b&c} Yes ^d | Yes ^{b&c} Yes ^d | No |
| | | <i>Supply</i> does not include <i>dispense</i> | | | | |
| NT | Act 2012 s7, s21, s65, s71(3) | <i>Supply</i> of a Scheduled substance includes: (a) sell the substance; and (b) provide the substance on prescription; and (c) provide the substance to a person in accordance with a Scheduled substance treatment protocol. (2) However, supply of a Scheduled substance does not include issue a prescription for the supply of the substance | Silent | Yes | Yes ^b Yes ^{d&e} | Yes ^b Yes ^{d&e} |
| Qld | Act 2019 s24; Regulation 1996, s67, s175, s263, s263A | <i>Supply</i> of a regulated substance, means sell or give the substance to a person. (2) However, supply of a regulated substance does not include – (a) if the substance is a medicine – administer the substance; or (b) if the substance is a poison – apply the substance; or (c) dispose of waste from the substance | Yes ^{b&e&f} Yes ^{b&g} Yes ^{i&d} | Yes ^{b&e&f} Yes ^{b&g} Yes ^{i&d} | Yes ^{b&e&f} Yes ^{b&g} Yes ^{p&d} Yes ^{h&d} Yes ^{i&d} | Yes ^{b&e&f} Yes ^{b&g} Yes ^{h&d} |
| NSW | Act 1966 s4, s10(4c-d), s17A; Regulation 2008 18(2), s53, s101, s170, s171 | <i>Supply</i> includes: (a) sell, dispense and distribute, and (b) supply, whether free of charge or otherwise, by way of sample or advertisement, and (c) supply, whether free of charge or otherwise, in the course of testing for safety or efficacy on persons or animals, and (d) agree or offer to sell or distribute, and (e) keep or have in possession for sale, dispensing or distribution, and (f) send, forward, deliver or receive for sale, dispensing or distribution, and (g) authorise, direct, cause, suffer, permit or attempt any act mentioned in paragraphs (a)–(f) | Yes ^k Yes ^h Yes ^{i&b} | Yes ^k Yes ^h Yes ^{i&b} | Yes ^k Yes ^h Yes ^{i&b} | Yes ^k Yes ^h Yes ^l Yes ^m Yes ⁿ |
| ACT | Act 2008 s24 | <i>Supply</i> – (a) includes the following: (i) sell (or offer or expose for sale); (ii) dispense; Note Dispense means supply on prescription (see dict). (iii) supply under a requisition or standing order; (iv) dispose of by any method for free (other than by discarding); but (b) does not include administer | Yes ^d Yes ^o | Yes ^d Yes ^o | Yes ^d Yes ^o | Yes ^d Yes ^o |
| Vic | Act 1981 s4, s13(bb), 14A, s22D-H; Regulations s39, s142 | <i>Supply</i> means – (a) supply, provide, give or deliver, whether or not for fee, reward or consideration or in expectation of fee, reward or consideration; (b) agree or offer for the purpose of supply as defined in paragraph (a), expose for the purpose of supply as so defined, keep or have in possession for the purpose of supply as so defined, send forward or receive for the purpose of supply as so defined; and (c) authorize, direct, cause, allow, suffer, permit or attempt to do any of the acts or things mentioned in paragraph (a) or paragraph (b) – and the derivatives of supply shall have corresponding meanings | Yes ^{p&d} Yes ^h | Yes ^{p&d} Yes ^h | Yes ^{p&d} Yes ^h | Yes ^{p&d} Yes ^h |
| Tas | Act 1971 s3, s25A; Regulations s62 | <i>Supply</i> , in relation to a substance, includes – (a) administer a substance, whether orally, subcutaneously, or by any other means; (b) dispense a substance on prescription; and (c) offer or agree to supply a substance | Silent | Silent | Yes ^{q&b} Yes ^{r&b&e} Yes ^{u&b&e} Yes ^{t&d} Yes ^s | Yes ^{q&b&e} Yes ^{r&b&e} Yes ^{u&b&e} Yes ^s |

- a. Requirement for prescription/prescriber order not specified
 - b. On prescriber order/prescription
 - c. If the supply occurs from a remote clinic AND there is no open pharmacy within 25 km AND the supply is not for the purposes of acute care or treatment relating to the implementation of a public health program
 - d. According to authorised protocol/standing order/Structured Administration and Supply Arrangement
 - e. If an authorised/approved nurse
 - f. To an outpatient or patient being discharged from a hospital in a rural area (approved nurse in this instance is hospital director of nursing or their delegate)
 - g. To an outpatient or patient being discharged from a hospital in an isolated practice area
 - h. If RIPEN endorsed
 - i. If a sexual health nurse
 - j. To patient/inmate of designated hospital/institution
 - k. If holding a personal authority or belonging to a class of persons for whom an authority has been issued by the Director-General and acting in accordance with that authority
 - l. Director of nursing of hospital where a pharmacist is not employed
 - m. RN in charge of a ward of a public hospital
 - n. Employed by ambulance service of NSW as a flight nurse
 - o. Medications already dispensed for the patient on their discharge from an institution
 - p. In a public health emergency
 - q. Working at an approved facility being a community health centre or medical institution at which is impractical for a medical practitioner to attend
 - r. Working at a day treatment centre or in vitro fertilisation clinic
 - s. Working for a palliative care service
 - t. Employed at Australian Red Cross Blood Service, lignocaine only
 - u. Employed in a correctional health facility, or a children and youth services facility, at which it is impractical for a medical practitioner to attend
- ACT, Australian Capital Territory. NSW, New South Wales. NT, Northern Territory. Qld, Queensland. RN, registered nurse. SA, South Australia. Tas, Tasmania. WA, Western Australia. RIPEN, Registration Standard for Endorsement of Registered Nurses (Rural and Isolated Practice).

Supply

The supply of medications may relate only to stages 4–6 of the MMC. However, where supply is authorised without a prescription, stages 1–3 of the MMC will also be occurring. For example, where an RN is authorised to supply any medication without an order from a prescriber, the RN is then required to assess and use clinical reasoning to determine the need for medication; make a decision about appropriate medication use either independently or according to a protocol; record information about the medication route, dose and timing; and the supply and/or administration of the medication to the patient.

Definition: Although the Acts in SA, WA, NT, Queensland, NSW, ACT, Victoria and Tasmania all define *supply*, the definitions are different. Acts in WA, Queensland and the ACT specifically mention that supply does not include *administer*, whereas in Tasmania the term *supply* includes *administer*.

Authorised actions for RNs: Table 3 summarises differences in authorised actions for RNs in relation to the supply of medicines. Twenty-one variable provisions relating to supply authorisations were identified.

Schedule 2 and 3 medications There is no national consistency relating to the supply of Schedule 2 or 3 medications by RNs (Table 3).

Schedule 4 medications There is no national consistency relating to the supply of Schedule 4 medications by RNs (Table 3).

Schedule 8 medications There is no national consistency relating to the supply of Schedule 8 medications by RNs (Table 3).

Administer

Traditionally administering a medication is stage 8 of the MMC. However, similar to the situation with supply of medications, where administration is authorised without an order from an authorised prescriber then steps 1–6 of the MMC may also be occurring.

Definition: *Administer* is a frequently used term in legislation. It is not defined in the Acts or Regulations of SA, WA, NSW, ACT, Victoria or Tasmania (Table 4).

Authorised actions for RNs: Significant variations exist regarding administration authorisations for RNs across Australian states and territories, summarised in Table 4. Due to their complexity and multitude, provisions regarding RNs and the administration of Schedule 4 medicines that are also vaccines have been excluded from this analysis. All findings regarding authorised actions in Queensland relate to authorisations made under the Health (Drugs and Poisons) Regulation 1996 which remains in effect until the new Medicines and Poisons (Medicines) Regulations 2019 have been finalised and enacted.

Schedule 2 and 3 medications There is no national consistency relating to the administration of Schedule 2 or 3 medications by RNs (Table 4).

Schedule 4 medications Nationally, RNs are consistently authorised to administer a Schedule 4 medication on the order of an authorised prescriber. Several variations exist nationally in additional authorisations for RNs relating the administration of Schedule 4 medicines (Table 4).

Schedule 8 medications Nationally, RNs are consistently authorised to administer a Schedule 8 medication on the order of an authorised prescriber. Several variations exist nationally in additional authorisations for RNs relating the administration of Schedule 8 medicines (Table 4).

Table 4: Definitions and authorised actions for *administer*

| State | Source | Definition of <i>administer</i> | Can an RN administer a medication? | | | |
|-------|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| | | | Schedule 2 | Schedule 3 | Schedule 4 | Schedule 8 |
| SA | Act 1984 s15, s18; Regulation s44 | Not defined | Yes | Yes | Yes | Yes ^a Yes ^b |
| WA | Regulation 2016 s54 | Not defined | No | No | Yes ^a Yes ^b | Yes ^a Yes ^b |
| NT | Act 2012 s22(2), s72 | <i>Administer</i> a Scheduled substance is to apply or introduce the substance to the body of a person or animal | Silent | Yes ^b | Yes ^a Yes ^b | Yes ^b |
| Qld | Act 2019 s26 | <i>Administer</i> a medicine means – (a) introduce a dose of the medicine into the body of a person or animal by any means; or (b) give a dose of the medicine to a person to be taken immediately. <i>Examples of administering a medicine</i> – • injecting a medicine into the body of a person or animal • putting cream on the skin of a person or animal • putting drops into the eyes of a person or animal | Yes Yes ^{c&b} | Yes Yes ^{c&b} | Yes ^a Yes ^{c&b} Yes ^{d&b} Yes ^{e&b} | Yes ^a Yes ^{c&b} Yes ^{d&b} Yes ^{e&b} |
| NSW | Act 1966 s10(4c); Regulations 2008 s58, s120, s170, s171 | Not defined | Yes ^a | Yes ^a | Yes ^a Yes ^c Yes ^{f&b} Yes ^{g&b} Yes ^{h&b} | Yes ^a Yes ^c |
| ACT | Regulations 2008 s75, s78, Schedule 1, 1.6 | Not defined | Yes ^a Yes ^b | Yes ^a Yes ^b | Yes ^a Yes ^b | Yes ^a Yes ^b |
| Vic | Act 1981 s13, s22D-H Regulations 2017 s39, s96, s97, s142 | Not defined | Silent Yes ^{c&b} Yes ^{e&b} | Silent Yes ^{c&b} Yes ^{e&b} | Yes ^a Yes ^{c&b} Yes ^{e&b} | Yes ^a Yes ^{c&b} Yes ^{e&b} |
| Tas | Act 2018 s25A; Regulations 2018 s31, s39, s64, s78K | Not defined | Yes | Yes | Yes ^a Yes ^b Yes ⁱ | Yes ^a Yes ^b Yes ^g |

a. On an order from an authorised prescriber

b. According to an authorised protocol/standing order/Structured Administration and Supply Arrangement

c. If RIPEN endorsed

d. If a sexual health nurse

e. In a public health emergency

f. If at a correctional facility

g. Individual written authorisation

h. If NDEC qualified and working at an NDEC authorised facility

i. Employed at Australian Red Cross Blood Service, lignocaine only

ACT, Australian Capital Territory. NDEC, Nurse Delegated Emergency Care. NSW, New South Wales. NT, Northern Territory. Qld, Queensland. RN, registered nurse. SA, South Australia. Tas, Tasmania. WA, Western Australia. RIPEN, Registration Standard for Endorsement of Registered Nurses (Rural and Isolated Practice).

Discussion

Nationally inconsistent medicines and poisons legislation and related legal instruments affect the capacity for RNs in Australia to understand and therefore practise confidently within their legal scope. With the burgeoning demand for healthcare services, changing models of health service delivery, and new and emerging health issues, it is vital that systems regulating health professional practice adapt quickly.

Features of the Australian legal system and the processes involved in effecting change to Acts and Regulations hamper the ease with which adaptations can be made to accommodate changing healthcare delivery needs, such as in the management of a public health outbreak or health professional staffing crisis.

The format and content of legislation pertaining to the use of medicines also vary considerably. Authorised actions for health professionals are difficult to locate, collate and interpret where they are not presented by profession, authorised action and the schedule of medicine, or where summary tables of authorised actions by profession are not provided.

Inconsistent definitions in the legislation also affect the ease with which legislation can be interpreted. Queensland is the only jurisdiction that defines all key terms. Nationally, terms such as

supply are used inconsistently or used in some contexts but not others. Moreover, the use of several terms to describe a single schedule of medicine both within and across jurisdictions makes interpretation more complex and confusing.

The 28 identified variants in how RNs are authorised to work with medicines seems an unnecessary burden on nurses who need to be able to work consistently across Australia. The greatest impact of these inconsistencies is likely to be in remote areas, where RNs have responsibility for more of the MMC than their urban counterparts. Where RNs are authorised to undertake extended practice with regards to medications, such as supplying medications according to authorised protocols, differences in required training and preparation are significant and these impact on workforce mobility and quality of care.

These are important policy issues in a context of greater equity of access to health care and medications for people living in remote Australia. A lack of consistency in legislation relating to how RNs work with medications in Australia is a hidden, systemic cause of inequity impacting on nursing practice and directly affecting the health of those who live in remote parts of the nation. By far the greatest proportion of the people affected are Aboriginal and Torres Strait Islanders. Eliminating this hidden, systemic inequity will, therefore, contribute to closing the gap in

life expectancy between Aboriginal and Torres Strait Islander and non-Indigenous Australians. Harmonisation of nursing practice in relation to all aspects of the medication management cycle via nationally consistent medicines legislation will improve equity of access to health care and medications. This will enhance the quality of care provided to those Australians whose health is generally poorest. However, this demands of decision makers a nationally collaborative approach and a willingness for policy and legislative reform efforts. An appetite and ambition for such reform has been characteristic in some areas of Australian health care, so it is really now just a question of the desire of decision-makers to act on this practical issue that will lead to improvements in health outcomes in remote Australia.

Limitations

This analysis has neither explored nor compared the legislative provisions relating to RNs and the possession of scheduled substances, nor the multitude of legislative requirements that exist for storing, labelling and destroying medicines. Also not explored are the requirements and provisions related to RNs and the administration of vaccines. The differing requirements of the state and territories regarding verbal orders from authorised prescribers have similarly not been explored. Although warranted, analysis of authorisations for both RNs who hold NP endorsement and authorisations for Aboriginal health workers and practitioners was not possible within the scope of this project.

Conclusion

Administrations of Schedule 4 and 8 medications according to an order from an authorised prescriber are the only actions authorised consistently for RNs across Australia. Other actions relevant to a specific schedule supported in one state or territory are not necessarily supported in others, and the regulated educational requirements for extended roles with medicines differ. This lack of consistency poses a significant risk to not only RNs working in remote areas but all RNs whose roles with medications exceed these two defined actions. A lack of uniformity between Australia's medicines and poisons legislation means RN practice will vary across Australia and patients may not receive a standard or universal level of care.

It is imperative to acknowledge that in Australia a health professional's individual scope of practice is defined jointly by legislation; their level of educational preparation, knowledge, skills and experience; the needs of the community; and the

policies and procedures of their employing organisation. Any or all of these elements may be either broader or more limited than legislated roles with medicines. With Australia's highly mobile workforce and high turnover rates in remote areas³³, inconsistencies in legislated authorisations regarding medicines may result in RNs working either suboptimally or outside their legal scope.

Little has been published about the effects of legislative requirements on nursing practice and health service delivery in remote Australia, where health status is generally poorer and where access to health services and health professionals is more limited than in other parts of the country²⁰. Additionally, although RNs who are not NPs are known to have been working in extended roles in remote Australia, little is known about how they are supported to undertake these roles involving medications. Further research is warranted to investigate the legislative models that best facilitate timely access to medicines in remote Australia and the education and experience that best prepare RNs to work in extended MMC roles within a quality use of medicines framework.

Access to essential medicines is a key component of the National Medicines Policy⁷. A lack of consistency between state and territory legislative instruments may affect people's timely access to medicines in remote Australia and have significant implications for their health.

Health service delivery involving medicines in remote areas needs to be consistent across Australia to ensure health outcomes and health professionals in remote areas are not unnecessarily compromised. The present situation poses a considerable risk to the health and rights of many Australians, particularly those living in very remote areas where the vast majority of the population is Aboriginal or Torres Strait Islander. It also poses a considerable risk to the nursing workforce who may knowingly or not be undertaking aspects of medication management that are not authorised in their state or territory. Significant collaborative effort cognisant of models of healthcare delivery and the needs of people in remote Australia is required to address the issues identified.

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