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Dear Prof McNeil

Thank you for providing AMA Queensland with the opportunity to provide feedback on the consultation paper *Medicines and Poisons (Medicines) Regulation*.

AMA Queensland is the state's peak medical advocacy group, representing over 9,600 doctors across Queensland and throughout all levels of the health system.

AMA Queensland wishes to state at the outset we will only be commenting on the proposed technical amendments to the *Medicines and Poisons (Medicines) Regulation* and not the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation* nor the *Medicines and Poisons (Pest Management) Regulation*.

We will now comment on individual sections of the proposed regulations.

1. Purpose of the *Medicines and Poisons Act 2019*

AMA Queensland agrees with the purpose of the *Medicines and Poisons Act 2019*

2. That a regulated substance must be dealt with in the 'authorised way'

AMA Queensland will ensure all members understand the fundamental principles of dealing with regulated substances in the 'authorised way'.

A person carries out a regulated activity in the 'authorised way' if they are authorised to deal with regulated substances, if they undertake dealing with those substances they are authorised to deal with, and if they comply with the requirements imposed under the legislation on how these dealings must be undertaken. The requirements for how the dealings are undertaken include compliance with Departmental Standards and the Substance Management Plan, if at a regulated place.

3. New categories of medicines

AMA Queensland understands why the terms restricted medicines and diversion-risk medicines have been developed but recommend that the regulations use one term for the categories; "high-risk medicine" and "monitored medicines" given that the medicines listed in Schedule 2, Part 2 of the Medicines Regulation and the medicines listed in Schedule 2, Part 4 of the Medicines Regulation are the same and the explanation

provided in the regulations for both “high-risk medicine” and “monitored medicines” is also the same.

4. The regulated activities (dealings) approved persons are authorised to carry out

AMA Queensland agrees with this section of the regulations.

5. Extended practice authorities

AMA Queensland understands that the MP Act (section 232(4)) enables the chief executive to make extended practice authorities (EPA) that state the places or contexts an approved person may deal with a regulated substance, imposing conditions on dealings with the substance, or requiring a person to hold particular qualifications or training.

AMA Queensland agrees with EPA’s being provided to dentists, specialist medical practitioners, Aboriginal and Torres Strait Islander health practitioners and Indigenous health workers, other allied health practitioners (i.e. anaesthetic technicians), QAS, first aid providers, veterinary surgeons and ship’s master.

AMA Queensland also agrees with EPA’s being provided to nurses and notes the expansion of scope for enrolled nurses working in an anaesthetic environment, equivalent to those proposed for anaesthetic technicians, as long as this is limited to retrieval of medication for doctors and anaesthetists.

AMA Queensland remains opposed to EPA’s specifically being provided to pharmacists and physiotherapists to allow Queensland Health to expand the current pharmacy UTI trial and the physiotherapy prescribing trial in emergency departments in public hospitals including authority for a regulated substance to be carried out under direction or supervision.

Section 54 of the regulations names certain classes of person who are able to prescribe. AMA Queensland recommends that Queensland Health to publish the scope of clinical practice for each ‘class of person’ in an easily accessible format including the formulary for prescribing. AMA Queensland would recommend each of these ‘class of person’ follow the *AMA 10 Minimum Standards for Prescribing (see attachment 1)*.

6. Emergency orders – COVID-19 response

AMA Queensland agrees with this section of the regulations.

7. New requirement for relevant practitioners to check the monitored medicines database (QScript) before prescribing, dispensing or giving a treatment dose of a monitored medicine for a patient, and to comply with the Departmental Standard – Monitored Medicine

AMA Queensland agrees that this technical amendment clarifies which practitioners are required to check the monitored medicines database before prescribing a monitored medicine, however, we still have concerns about how practical this requirement will be for medical practitioners working in residential aged care facilities (RACF), medical practitioners working in accident and emergency or medical practitioners doing ward rounds in public and private hospitals. This is despite QScript being accessible via mobile and tablet devices (as stated in the *Report No.8, 57th Parliament Economics and Governance Committee May 2021*) as AMA Queensland believes this requirement is administratively burdensome.

The expansion of classes of persons in the regulations provides Queensland Health with the flexibility of changing the regulations to suit the Queensland Governments policy of supporting task substitution where non-medical practitioners are provided with the authority to undertake tasks previously undertaken by medical practitioners.

8. The How: Requirements for dealings with medicines

AMA Queensland agrees with this section of the regulations.

9. Offences and penalty infringement notices

AMA Queensland agrees with this section of the regulations. Thanks again for providing AMA Queensland with the opportunity to provide feedback on the consultation paper *Medicines and Poisons (Medicines) Regulation*.

Yours sincerely



Professor Chris Perry
President
AMA Queensland



Dr Brett Dale
Chief Executive Officer
AMA Queensland

10 Minimum Standards for Prescribing

August 2019

Introduction

This Standards document has been informed by the [AMA Code of Ethics](#), the [AMA Guidelines for Doctors on Managing Conflicts of Interest in Medicine](#), the [AMA Position Statement on Medicines](#), and the National Prescribing Service (NPS) [Competencies Required to Prescribe Medicines: Putting quality use of medicines into practice](#).

The prescribing of medications forms only a part of a patient's treatment plan and the appropriateness and therapeutic benefit of any prescribed medicine must be considered within the continuum of an individual patient's care. Good patient care involves communication and collaboration between all the health practitioners (medical and non-medical) that form a patient's multidisciplinary health care team and are involved in that patient's care.

Purpose

These guidelines have been developed to make it clear the minimum standards that must be required of all prescribers authorised to prescribe S4 and S8 medications.

Context

A range of health professionals can prescribe S4 and S8 medications. The primary prescribers are doctors (medical practitioners) but dentists, optometrists, midwives and nurse practitioners also have prescribing rights within regulated limitations. The AMA wants to ensure that all prescribers understand they are part of a patient's health care team and in the interests of patient safety and quality of care it is important that they work collaboratively with the patient's nominated medical home and operate only within their scope of practice.

Who do these Standards apply to?

These standards are principally concerned with health services, General Practitioners and other medical professionals. Health Services may be public or private. These Standards address emergency care, admitted care and non-admitted care episodes.

It is the view of AMA that these standards should apply to all authorised prescribers.

The 10 Standards for Prescribing

Standard 1: Prescribing by non-medical health practitioners should only occur within a medically led and delegated team environment in the interests of patient safety and quality of care.

Medical practitioners are currently the only health professionals trained to fully assess a person, initiate further investigations, make a diagnosis, and understand the full range of clinically appropriate treatments for a given condition, including when to prescribe and, importantly, when not to prescribe medicines.

Standard 2: There must be no pecuniary or non-pecuniary benefit to the prescriber related to the choice of medicines prescribed or the dispensing of those prescribed medicines.

To ensure there is no perceived or actual conflict of interest in prescribing a medication to a patient, no benefit to the prescriber can be afforded for prescribing a specific medication or combination of medicines or the dispensing of those medications. In addition, to facilitate safer prescribing and ensure a system of checks and balances the functions of dispensing or administering medicines must be separate from the function of prescribing.

Standard 3: Before prescribing establish a therapeutic relationship with the patient and perform a comprehensive medicines assessment to identify what other medicines, including complementary medicines, the patient is taking and consider any implications to the patient's treatment plan.

The prescriber must use appropriate communication strategies to establish a therapeutic relationship with the patient, and through this relationship determine the patient's current use of medications, prescribed or otherwise, including any recent additions or exclusions, and any potential risks for medication non-adherence or contraindication. With this information consider the implications to the patient's treatment plan including revision of medications, mechanisms to support adherence, if needed, therapeutic benefit; and referral to other health professionals where appropriate.

Standard 4: Prescribers ensure they:

- a) consider the necessity and appropriateness of medications in managing the patient's health care needs,
- b) choose the most suitable and cost effective medicines when medicines are considered appropriate, taking into account the efficacy, potential for self-harm, and the ability of the patient to adhere to the dosage regimen,
- c) advise patients how to use their medicines safely and effectively, and that patients are aware of the relevant side effects of prescribed medications as well as relevant interactions between medications, and
- d) report any adverse reactions to the TGA.

Prescribers need to ensure that prescribed medications align with achieving the patient's health care objectives. Prescribers also need to ensure that patients understand the purpose of their medication and are aware of relevant side effects and contra-indications which could lead to an adverse medication event, and the need to contact them if there is a problem.

Standard 5: Prescribers must maintain clinical independence.

Prescribers must exercise their professional judgment in the care and treatment of their patients without undue or inappropriate influence by external parties.¹

Standard 6: Prescribers must:

- a) operate only within their scope of practice as set by their professional Board, and
- b) comply with state, territory and Commonwealth legislative requirements, including restrictions under the Pharmaceutical Benefits Scheme (PBS) system.

¹ [WMA Declaration of Seoul on Professional Autonomy and Clinical Independence](#)

Prescribers must have a clear understanding of the legislative rules and regulations that govern their prescribing, the scope of their practice and ensure they refer the patient to other health professionals as required.

Standard 7: Prescribers work in partnership with the patient to set therapeutic goals and with other health professionals as appropriate to select medicines and to tailor and implement a treatment plan.

This ensures the provision of patient-centred and collaborative care aimed at delivering quality patient outcomes. Within any collaborative arrangement with a non-medical health practitioner there must be a system of mandatory referral to a registered medical practitioner where appropriate clinical criteria and outcomes are not achieved within a specific time frame.

Standard 8: Prescribers provide clear instructions to delegated prescribers within the health care team and to other health professionals who dispense, supply, or administer the prescribed medicines.

This reduces the likelihood of a medication related adverse event.

Standard 9: Prescribers with the patient consent communicate with other health professionals within the patient's health care team about the patient's medicines and treatment plan.

This reduces the risk of fragmentation of care and promotes the coordination of holistic care across the health care team.

Standard 10: Prescribers monitor and review the patient's response to treatment and adjust the treatment plan as appropriate.

This ensures the appropriateness of care.
