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Project Director
Real-Time Prescription Monitoring Implementation
Department of Health and Human Services
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Email: SafeScript@dhhs.vic.gov.au

To the Project Director,

RE: Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018

Thank you for the opportunity to provide feedback to the *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018* ('the draft Regulations').

AMA Victoria has been a strong advocate for electronic systems to collect and report real-time dispensing data. We commend the state Government for its commitment to the implementation of SafeScript and **continued consultation** with stakeholders on the legislative framework. Continued consultation with, and responsiveness to, external stakeholders is essential during the pilot and implementation phases.

AMA Victoria provides the following comments by way of feedback.

Exclusion of codeine, ongoing adjustment of regulated medications (poisons)

AMA Victoria is very concerned about the exclusion of codeine from the current list of high-risk medicines to be monitored through SafeScript.

The Austin Health literature review in relation to inclusion of Schedule 4 prescription medicines into the real-time prescription database acknowledges the difficulties in estimating the real harm of codeine. Local peer-reviewed literature supports that the harm of codeine is no greater than that of other Schedule 4 medicines, like antidepressants examined in the study. The authors acknowledged the limitations of their study, in particular that monitoring of Schedule 8 opioids might lead to the chilling effect and this might accentuate any substitution (or squeezed balloon) effect seen with codeine.

AMA Victoria advocates that codeine should be included in the first tranche of substances in the real-time prescription monitoring system. The 18 month introductory period provides ample time for analysis of the use and misuse of codeine and an opportunity to adjust the draft Regulations. Further to that, AMA Victoria recommends that the 18 month introductory period provides an opportunity to evaluate substances of emerging concern to be included in the monitoring system and others that might need to be excluded from the system if they are subsequently shown not to pose a significant patient safety risk.

Electronic prescription capabilities

The Regulations provide that:

After an 18 month introductory period to allow health practitioners to familiarise themselves with the system, it will be mandatory to check SafeScript prior to writing or dispensing a prescription for a high-risk medicine.

AMA Victoria submits that a minority of general practitioners (GPs), a majority of psychiatrists and other non-GP specialists, and the majority of hospitals do not have electronic records and/or associated electronic prescription capabilities.

The use of SafeScript is also predicated on consistent uninterrupted internet connectivity - which cannot be assured at any given time throughout Victoria.

Many private psychiatrists do not use a desktop computer during patient encounters, for clinical reasons, and record clinical notes by hand.

We have identified that many private psychiatrists will either need to set up electronic prescription capabilities, or alternatively have capability through another electronic device to access the portal. Essentially, some private psychiatrists will be required to change their entire practice. We understand this is a major change for a large number of private clinicians and a cause of significant disruption to clinical practice.

For psychiatrists nearing retirement, the roll out of SafeScript might compel some psychiatrists to seek early retirement. This could lead to a loss of workforce at a time when mental health resources are stretched.

Other specialists such as surgeons and anaesthetists in private practice, writing prescriptions for postoperative pain management may also encounter barriers to ready access to SafeScript "on the run".

AMA Victoria requests the state Government to:

- as a matter of urgency, commence targeted communications through all Specialist Colleges well ahead of the implementation of SafeScript to ready them for the 18 month grace period for non-GP specialists,
- provide targeted education to private psychiatrists and other doctors who do not use clinical prescribing software to understand and utilise electronic access to SafeScript so they can continue to safely manage patients with addiction problems, taper prescription doses and provide effective drug counselling without risk of incurring onerous financial penalties or inadvertently risking patient harm, and
- review IT capacity in emergency departments and at discharge planning in public health services to ensure prescribers will be able to meet the requirements under the law.

Penalties and exemptions

We understand that a penalty in excess of $15,000 (100 penalty units) will apply to practitioners who fail to take all reasonable steps to check the monitored poisons database before prescribing or supplying a high-risk medicine.

Victorian Coroner John Olle recommended that the real-time prescription monitoring system should be public health-oriented and not punitive.[1] AMA Victoria regards the financial penalty as excessive – particularly in the instance of a first breach, AMA Victoria believes that the SafeScript database is a useful clinical decision support tool but that the punitive ramifications of the draft Regulations warrant further scrutiny. Precedents overseas have served to highlight the danger that prescribers might avoid prescribing, or make suboptimal adjustments to medication doses in response to increased regulation and surrounding scrutiny of the dispensing framework.[2]

AMA Victoria supports that in most circumstances, a medical practitioner should check the database and consider the information on the database before prescribing a monitored supply drug to a patient. However, AMA Victoria raises some concerns around the exemption provisions of the draft Regulations.[3]

Exempting hospital emergency departments from mandatory reporting requirements

Exemptions to mandatory checking of the database currently include hospital inpatients, patients treated in emergency departments, prisoners, residents in aged care facilities and palliative care patients with incurable medical conditions.

AMA Victoria understands the rationale behind this exemption, as access to the database is especially difficult in emergency settings. AMA Victoria cautions that many patients who seek drugs

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[1] Victorian State Coroner, Her Honour Judge Sara Hinchey, "Submission to Inquiry into Drug Law Reform," 2017.
[2] Austin Health, "Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system," 2017.
[3] Austin Health, "Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system," 2017.

of dependence present to emergency hospital departments if they are unable to obtain their drug of choice elsewhere.

AMA Victoria believes that there needs to be adequate information technology infrastructure within health services, like hospitals and emergency departments, to enable access to SafeScript and meet the requirements of prescribing at discharge.

Requirement to ascertain if person under palliative treatment is drug-dependent

Health professionals have existing legal and professional requirements to take all reasonable steps to ensure a therapeutic need exists before prescribing a medicine.

'Reasonable steps' is not defined in the draft Regulations or Principal Regulations[4]. The Regulatory Impact Statement (RIS) provides an example of a prescriber who has been requested by a patient new to their clinic to prescribe a high-risk medicine. A doctor in these circumstances would be expected to verify the patient's medication history before deciding on the appropriateness of treatment.

The RIS provides a sensible example. However, s132H includes an exemption for providers to check the database, provided the prescriber is satisfied that the person is not drug-dependent. This clause implies that prescribers must take reasonable steps to ascertain whether a person under palliative care is drug-dependent.

AMA Victoria submits that this requirement is not practical and will only serve to create an unreasonable burden on prescribers or perversely prevent compassionate care of a terminally ill drug-dependent patient.

Risk of perverse outcomes for psychiatric patients with dual diagnosis conditions

AMA Victoria believes that the punitive provisions of the draft Regulations need to be balanced against likely perverse outcomes that could arise even from soundly developed policies.

In the psychiatric context, we know that patients with psychiatric illness often seek drugs of dependence. Dual diagnosis conditions of drug dependence and underlying psychiatric illness are prevalent in Victoria.

Highlighting the prevalence of dual diagnosis conditions, a 2014 study amongst a segment of Melbourne's community who experience chronic homelessness found that 69% met the criteria for a psychiatric disorder diagnosis and a current alcohol or substance abuse or dependence disorder.[5]

Structures are put in place by psychiatrists, such as more frequent pick-up of medication, for example weekly small quantities of medication at a time, to ensure therapeutic benefit optimisation but also to minimise risks. Therapeutic doses of high-risk medications are prescribed by psychiatrists on careful consideration of the patient's history, prior treatment and clinical formulation.

AMA Victoria cautions that if the real-time prescription monitoring system inhibits doctors' appropriate prescribing, it may have the concomitant perverse outcome of increasing intentional overdose deaths. If psychiatrists take no risks, and always restrict prescription of medication to people with mental illness, there is a concern that this may impede the development of trust in the clinician-patient relationship. It may also hinder the development of self-care strategies in psychiatric patients.

Software integration and internet connectivity

AMA Victoria supports the implementation of a mandatory SafeScript database provided the system software is automatic, quick and does not interrupt clinical workflow.

Software integration of the real-time prescription monitoring platform is highly desirable, if not essential. Our members have made it clear to us that the RTPM database should be integrated with practice software, for ease of use.

Further, it is very important to acknowledge SafeScript's dependency on live internet connections. In some rural practice settings, internet connectivity is poor or absent.

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[4] In the draft Regulations, the *Drugs, Poisons and Controlled Substances Regulations 2017* are called the Principal Regulations.

[5] O'Donnell et.al. "The Trauma and Homelessness Initiative." Report prepared by the Australian Centre for Post-traumatic Mental Health, in collaboration with Sacred Heart Mission, Mind Australia, Inner South Community Health and Vincent Care Victoria, 2014.

In urban settings, fibre to the node NBN connections can be of variable quality and subject to low speeds and dropouts.

AMA Victoria strongly advocates that no penalty should **ever** apply if internet service can be shown to have been poor or unavailable.

Use of term 'poison' in legislative framework

The draft Regulations make reference to 'poisons'. We understand the legal contextual framework underpinning use of this term.

Given that doctors prescribe 'medicines', AMA Victoria cautions that use of the word 'poison' in relation to these substances outside the definitions within the legislation should be avoided e.g. in communications.

Please contact Nada Martinovic, Senior Policy Adviser, on (03) 9280 8773 or nadam@amavic.com.au if you wish to discuss further.

Yours sincerely

Dr Lorraine Baker

PRESIDENT