AMA Victoria's submission to the Victorian Department of Health and Human Services review of the *Drugs, Poisons and Controlled Substances Regulations 2006*

AMA Victoria welcomes the opportunity to provide input into developing a draft Consultation Document for the review of the *Drugs, Poisons and Controlled Substances Regulations 2006.*

AMA Victoria believes that there are several opportunities to improve the effectiveness and efficiency of the current scheme and improve the process involved for doctors, patients and the administrators of the scheme. System improvements would also support doctors to work in the best interests of their patients and to prescribe medicines safely and appropriately.

Usability of Documentation

Online forms should improve efficiency, accuracy and safety, however the current forms available through the online portal are cumbersome and take doctors additional time and effort to complete.

Current electronic forms are not compatible with the range of medical software used in practices and cannot populate or auto-fill relevant patient information. This lack of interoperability aggravates doctors, causing additional time consumption, potentially increases incidence of errors and often requires additional administrative follow-up. AMA Victoria regularly receives feedback that online forms often take longer to complete than the hard copy. Poor usability means it is faster for doctors to complete the required paperwork by hand.

In addition, forms often have to be printed, given to reception staff to scan and then saved back into the patient file as a new document. This increases workload for doctors and practice staff, increases the burden on computer and electronic storage systems and means that the information is not easily retrievable.

The overall assessment by AMA Victoria is that the current regulations and processes have not kept pace with technological changes, meaning that the electronic systems that should streamline processes are actually creating a more burdensome system.

New technologies are constantly being developed and the new Regulations must ensure that the administrative processes underpinning these are able to ensure interoperability with new systems such as *My Health Record* (PCEHR), real-time prescription monitoring systems and Electronic Transfer of Prescription (ETP), as well as current medical software programs.

AMA Victoria recommends that software system interoperability and the ability to adopt new systems and processes be a fundamental aspect of the new Regulations.

Red-tape requirements place a heavy burden upon medical practices and detract from the time they are able to spend on patient care.

The efficient and effective operation of the *Drugs, Poisons and Controlled Substances Act* relies upon accurate completion of medical forms. Ultimately medical practitioners have a professional obligation to ensure that all forms comply with minimum professional standards of relevance, and contain the minimum amount of necessary information for the purpose intended, while respecting the doctor's opportunity costs and accountability.

The use of standardised electronic forms has great potential to improve patient safety through improved clarity and reduced transcription errors. However, such forms must be easy to use, streamline processes and respect patient privacy. AMA Victoria considers the current online forms do not meet these requirements.

The AMA has developed 10 Minimum Standards for Medical Forms which are designed to instruct, guide, and measure the performance of organisations that rely upon medical practitioners to assist the effective conduct of the Regulations. AMA Victoria considers it would be helpful to have these elements in the form to support greater use.

AMA's 10 Minimum Standards for Medical Forms are:

Available & Accessible

1. The form is available in an electronic format that is compatible with existing electronic general practice medical records software.

2. Forms are distributed through medical software vendors. Access to forms does not require web surfing during consultations, nor form-filling online.

Value GP Time

3. The form has a clear notation that states that medical practitioners may charge a reasonable fee for their services and whether the services are rebatable by Medicare or other insurers.

Not Onerous & Respect Privacy

4. Demographic and medical data can be selected to automatically populate the electronic form with adequate space being provided for comments.

5. Only information essential for the purpose is requested and must not unnecessarily intrude upon patient privacy.

6. Forms do not require the doctor to supply information when a patient can reasonably provide this in their own right.

Easy to Administer

7. A copy is saved in the patient electronic medical file for future reference.

8. Data file storage size is kept to a minimum.

9. Prior to their release, forms are field tested under the auspices of a recognised medical representative organisation such as the AMA and the RACGP in association with the MSIA (Medical Software Industry Association).

10. Consideration should be given to future compliance with encrypted electronics transmission capability, in line with new technologies being introduced into general practice.

AMA Victoria recommends that the Department of Health and Human Services adopt these standards as minimum requirements for all documentation required under the *Drugs, Poisons and Controlled Substances Regulations* in the future.

Communication, Timeliness and Flexibility

AMA Victoria regularly receives feedback that communication practices between the Department and doctors are inefficient and slow.

The current turnaround time for permits is inappropriately long. Ten years ago the average turnaround time was one to two days. Since then, bureaucratic requirements have slowed these processes and now it is not uncommon for them to take weeks. Anecdotal reports indicate that patients, particularly those with drug seeking behaviour, are well aware of the current response times. AMA members have indicated that they have had comments from patients such as "if you give me a script it will take three months for them to catch up".

Awareness of the significant delays in the system among not only doctors, but patients, indicates the serious inherent problems within the current system.

AMA Victoria recommends that the new Regulations introduce improved processes to ensure appropriately efficient turnaround times.

The current system is inflexible and incapable of dealing with urgent situations. The new Regulations must have appropriate mechanisms to allow for emergency prescribing without the need to telephone for a permit. Prescribing under these emergency special circumstances should be allowed for under the new Regulations, with provisions that a full application for a prescribing permit be received within 1-2 weeks. Where a full permit is not granted, a permit covering the single prescription should be issued. Doctors know their patients, and the decision to prescribe a medication that requires a special permit is not made lightly or inappropriately. Where patients display drug seeking behaviour, a doctor would be well aware of this and would not consider it to be an emergency situation.

AMA Victoria recommends that the new Regulations allow some flexibility for doctors to prescribe in urgent or emergency situations, where a doctor reasonably believes that prescribing a certain drug is in the best interests of a patient.

Communication from the department can be poor, particularly with respect to notification that a current permit is due to expire. To ensure that there is no lapse of permits, and to ensure that doctors do not inadvertently prescribe without a current permit, clinics must manage their own records. Often a doctor will not realise that a permit is due to expire until it has already expired, and the doctor is faced with a patient in need of a prescription. The new Regulations should include a requirement that notification is provided by the Department when a current permit is due to expire. This notification should be sent by fax, email or secure messaging (as per the practice preferences) with sufficient time to allow doctors to complete the necessary documentation to renew the permit, where appropriate, or initiate a plan with the patient to cease the medication.

AMA Victoria recommends that the Department implement a timely "notification of expiring permit" process as part of the new Regulations.

Timelines outlined in the Regulations must match the reality of the current health system and must be evidence based. For example, the current regulations suggest that where needed, the time to seek the specialist advice required for certain scripts should be a maximum of three months. This time-frame is at odds with the current health system. In the case of seeking an appointment with a pain specialist, the wait for a public pain clinic can be three years and for many patients a referral to a private specialist is not a financially viable alternative.

AMA Victoria recommends that the new Regulations align with the current access and service availability of the Victorian health system and only require specialist review where there is a robust evidence base to support the need.

Knowledge of current regulations

Most General Practitioners are sufficiently aware of their roles and obligations under the *Drugs, Poisons and Controlled Substances Regulations*, however, some may not be aware and could be inadvertently breaching these requirements. This is a particular problem in relation to the laws and requirements for the use and prescribing of Schedule 8 drugs.

Doctors are typically time poor and have an ever-growing list of new information with which they need to be familiar. The Regulations sometimes lack clarity and ease of use, may appear inconsistent, may be poorly communicated, difficult to access when required, and some provisions may change over time. These impediments can make it difficult for doctors to remain up to date with current requirements and to appropriately adhere to the Regulations. Unless information is relevant and provided in a timely, easily accessible and usable format, these barriers may affect doctors' application of the Regulations.

AMA Victoria recommends information is relevant and provided in a timely, easily accessible and usable format

The poor communication processes and the complexity and rigidity of the current regulations, may result in some GPs unintentionally prescribing outside the requirements outlined in the Regulations. This may expose doctors to legal action, although they may have acted in a medically appropriate way and in the patient's best interests, with good intention. The new Regulations should provide safeguards for doctors in this situation, particularly where the mistake is a first one, and allow for education in place of punitive measures.

AMA Victoria recommends that reasonable protections be given to doctors who inadvertently prescribe without a permit and that education about the law is a first response before punitive action.

One way to ensure that all doctors hold an appropriate level of knowledge regarding their roles and responsibilities under the *Drugs, Poisons and Controlled Substances Regulations* is to include a minimum level of knowledge for all doctors in General Practice as part of accreditation requirements. This would ensure that all doctors have a basic understanding of the law and will reduce mistakes or inadvertent prescribing.

Another key area where the knowledge of many doctors is occasionally lacking is off-label prescription of medications. Doctors would benefit from additional improved information from the Department on off-label prescribing.

AMA Victoria recommends that General Practice accreditation include a requirement that doctors show they hold a minimum level of knowledge regarding their role and responsibilities under the Drugs, Poisons and Controlled Substances Regulations.

Quick guides and fact sheets are useful but should use plain English and, where possible, be able to be read and understood in their own right. Phrases such as "Accordingly, in regulation 27(a)…" or "a person referred to in regulation 25" make the Guide difficult to apply in practice and require the doctor to have a full copy of the Regulations open as they attempt to comprehend what is required of them.

Information documents provided by the Department should not replace the current Regulations, but should provide easily accessible and coherent advice for doctors seeking to clarify an aspect of the Regulations.

AMA Victoria recommends that the Department provide user-friendly information sheets and user guides for doctors to navigate the new Regulations.

As part of the new Regulations, AMA Victoria encourages the Department to develop a formal training program for General Practitioners, to provide face-to-face education sessions to ensure that doctors are properly informed of their roles and responsibilities under the Act. AMA Victoria would be keen to engage with the Department to develop and deliver an accredited training program for doctors across Victoria. A formal, structured, education program would allow doctors to receive the information they need, in a reliable and functional format, and to ensure they are complying with all relevant laws and regulations.

AMA Victoria recommends that the Department provide a formal education program to inform doctors of their roles and responsibilities under the existing legislative framework.

A key step in ensuring the effective implementation of the *Drugs, Poisons and Controlled Substances Regulations* is the development and implementation of real-time prescription monitoring. Accessible by both doctors and dispensing pharmacists, this system would provide an additional safety-net to protect against inappropriate prescribing and dispensing.

An electronic system will collect and report dispensing data relating to controlled drugs, providing a single source of data for prescribers, pharmacists and state and territory health departments to identify problems of forgery, dependency, misuse, abuse and prescription shopping/“doctor shopping”.

AMA Victoria recommends that the Department prioritise the implementation of real-time prescription monitoring and ensure that the new Regulations are flexible enough to accommodate this system.

AMA Victoria looks forward to a cooperative consultative dialogue with the Department on what it sees as an important issue.