Joint GPDV / RACGP Submission on DHS Draft Replacement Regulations for the Drugs, Poisons and Controlled Substances Regulations 1995

September 2004

Introduction

General Practice Divisions – Victoria (GPDV) is the peak body for the thirty divisions of general practice in Victoria. GPDV supports divisions in their endeavours to ensure a skilled, viable and effective general practice workforce, to improve the health and well-being of the people of Victoria. Every Victorian division of general practice provides ongoing practical support and direction for systems change within practices to improve the quality of GP services. GPDV provides education for division staff whom support the accreditation of general practices.

The Royal Australian College of General Practitioners (the RACGP) is the national leader in setting and maintaining the standards for quality practice, education and research in Australian General Practice. The RACGP has developed a set of national standards for general practices, with the aim of engaging the profession in a comprehensive process of continuous quality improvement. These standards are implemented through an independent system of practice accreditation. To date, approximately 85% of Australian general practices have been accredited through this system. The RACGP is currently reviewing its standards for general practice.

Commitment to Safety and Quality

Both the RACGP and GPDV strongly support and help to facilitate the adoption of systems that enhance the quality of general practice services, and that reduce the risk of harm to patients. We fully support the intent of the *Drugs, Poisons and Controlled Substances Act 1981* which provides a framework for the protection of the Victorian public from the harm which could follow from the misuse or abuse of the drugs and poisons which come under the control of the Act.

An Effective Regulatory Framework

Furthermore, both organisations support the principles for good government regulation that have been set out by the Victorian Competition and Efficiency Commission (VCEC). We believe that the current set of Drugs, Poisons and Controlled Substances Regulations (1995) pose unnecessary costs and efficiency burdens on general practices, the vast majority of whom are small businesses. In the remainder of the document, we comment on the regulations that we believe should be amended so that the intent of the Act is met whilst the compliance burden on general practice businesses is minimised. Where we have no comment on DPU proposed changes one way or the other, we make no reference to those proposed changes.

Suggested Comments on Regulatory Amendments

Regulation 23

DPU Proposed Change: That the regulation be changed to allow the Secretary to approve prescriptions other than in the handwriting of the prescriber. This is intended to allow approval of computer generated paper prescriptions, and electronic generation and transmission of prescriptions. As yet, a satisfactory form of wording has not been identified.

RACGP/GPDV Comment: We strongly support a change to the regulations in this regard. In Victoria, 93.4% of practices prescribe electronically, compared with the national average of 91.3%. In four divisions of general practice, 100% of practices prescribe electronically.

Protection of the integrity of information printed on electronic prescriptions, the integrity of the transaction itself, and the prevention of multiple forgeries can be ensured by mandating the signature of the prescribing medical practitioner on the electronic prescription.

Where electronic prescriptions are e-mailed to suppliers of poisons, authentication (as well as confidentiality) can be assured through the use of digital keys and certificates ("public key infrastructure" or PKI). Essentially, this technology provides the prescriber with a key to scramble information to be sent electronically, and provides the supplier with a key to unscramble the information upon reception. It is the key that assures authentication of the identities of both parties.

There is an existing regulatory structure in Queensland with respect to computer generated prescriptions – Appendix D of the Queensland Health Environmental Health Unit's document "The Health (Drugs and Poisons) Regulation 1996: What Doctors Need to Know" which could provide guidance if the DPU is not already aware of it.

Regulation 25

DPU Proposed Changes: No change.

RACGP/GPDV Comment: If as suggested above in our comment about change to Regulation 23 the signature of a prescriber would satisfy a supplier of poisons in regard to its authenticity, then Regulation 25 would need to be amended so that the supplier could supply a Schedule 8 or Schedule 9 poisons if he or she is familiar with the *signature* of the purported prescriber, rather than the *handwriting* of the purported prescriber.

Regulation 32

DPU Proposed Changes: No change.

RACGP/GPDV Comment: The requirement to store any Schedule 4 poisons in a lockable storage facility in general practice is excessive in view of the low level of risk posed to the public. It creates unnecessary inefficiencies within general practices, which are required to administer Schedule 4 poisons (particularly immunisations) on a regular basis. These inefficiencies mean that time is taken away from patient care. A change to this regulation is required to ensure compliance to its intent. Furthermore, as currently formulated, this regulation contravenes the Principles of Good Regulation as formulated by VCEC – that regulation should achieve desired outcomes whilst minimising inefficiencies.

We recommend that Regulation 32(2), which applies to pharmacists, should also apply to general practitioners or nurses approved under Regulation 5(4) to be in possession of Schedule 4 poisons. That is, we recommend that in general practice, Schedule 4 drugs must be held in areas to which the public does not have free access and to which only a doctor or person authorised by a Health Services Permit has access. This change would increase compliance with the intent of the regulation, whilst reducing inefficiencies within general practice businesses.

Regulation 33

DPU Proposed Changes: There is an amendment to permit the storage of small quantities of Schedule 8 and 9 poisons required for emergency use in storage facilities of lesser security than is generally allowed.

RACGP/GPDV Comment: We agree with the addition of sub regulation (4).

Sub regulation (2) stipulates that the storage facility used to secure Schedule 8 and 9 poisons is only used for that purpose. In general practice, it is common practice that safes, which are significantly expensive to purchase in order to meet the stringent guidelines for the safe storage of poisons, are used for dual purposes such as the storage of money. We are not aware of any evidence to support the conjecture that the public will be more protected from harm if safes are only used for a single purpose. The important point is that Schedule 8 and 9 drugs are securely stored. We believe that they would be securely stored without sub regulation (2). Therefore we recommend that sub regulation (2) be omitted. In reference to VCEC Principles of Good Regulation, sub regulation (2) imposes unnecessary burdens on Victorian businesses and therefore the community and should be omitted.

Regulations 34 and 35

DPU Proposed Changes: No changes.

RACGP/GPDV Comment: Above, we recommend the omission of sub regulation (2) within Regulation 33. Were this to occur, Regulations 34 and 35 would need to be amended so that a person to whom the regulation applies may open the storage facility used to store Schedule 8 or 9 poisons to access its contents, *whatever those contents may be*, provided that the facility is immediately locked thereafter.

Regulation 45

DPU Proposed Changes: Two options: Option 1 would maintain the Regulation but clarify that it only applies to nursing homes as was originally intended when the Regulation was originally introduced; Option 2 would remove reference to who may administer Schedule 4, 8 or 9 poisons in a nursing home.

RACGP/GPDV Comment: A removal of the requirement for aged care facilities to ensure that Schedule 4, 8, or 9 poisons are administered only by a medical practitioner, pharmacist, dentist, authorised optometrist or nurse would mean that responsibility for the administration of poisons to nursing home residents could be left to Personal Care Workers (PCWs) or carers who have little if any understanding of pharmacology, pharmokinetics and the risk management required to adequately administer poisons to these patients.

This view is supported by the GP Residential Aged Care Interface Sub-Committee of the Victorian Advisory Committee on General Practice (VACGP), who released a report in 2003 on the interface between general practice and aged care systems and its impact on the care of patients in aged care facilities[1]. Medication management was nominated as the stand out area for improvement, with concern expressed by all surveyed regarding the potential for error leading to poor health outcomes for residents:

> GPs were… concerned about the administration of medication, in particular the potential for differences between Webster packs and drug charts… Agencies and Carers also expressed strong concern over the potential for error with scripts, Webster Packs and illegible handwriting… PCWs are able to administer medication from Webster packs (Blister Packs). The PCW/PCAs don't necessarily have the education or knowledge required for making clinical judgements such as knowing when to administer (pp29-31).

Given that personal care workers and carers are not necessarily trained to administer Schedule 4, 8 or 9 poisons, we believe that Option 2 could significantly compromise the care provided to residents in aged care facilities. Therefore we support Option 1.

Additional Comment: Drug Storage

It is our understanding that the DPU prohibits the pooling of Schedule 8 and 9 poisons that are the responsibility of individual medical practitioners. This requirement encourages larger group practices (particularly those with four or more general practitioners) to purchase and store quantities of these poisons in excess of need, which has two negative outcomes. Firstly, the practice becomes more of a target for those seeking illegal access to these poisons due to the large quantity held on site. Secondly, a greater proportion of poisons expire which entails a significant waste of public money.

We believe that the DPU should actively encourage the pooling of Schedule 8 and 9 poisons. This would help avoid the problems outlined above. For example, a ten-doctor practice might feel that holding five pethidine 100mg, 5 morphine 15mg and 5 morphine 30mg ampoules on site as being adequate – a total of 15 narcotic ampoules, which could be pooled and accessible by all practitioners on a needs basis, with stringent recording requirements in place to ensure proper tracking of the poisons with the responsibility placed in the hands of the practice principal. However, a requirement that each doctor store their own ampoules would mean that up to 150 ampoules would need to be ordered. This obviously is an increased risk to the public, and would lead to more drug expiries and wastage of public monies, as currently happens.

Additional Comment: Health Service Permit Fees

Our preference is for the abolition of the system of health service permits, as we are not aware of any evidence to support its existence. The number of nurses working in Australian

[1] Victorian GP Residential Aged Care Interface Sub-committee. 2003. *Report*. Sub-committee members: Aged Care Association Victoria, Aged Care Standards and Accreditation Agency, Australian Medical Association Victoria, Carers Association Victoria, Department of Health and Ageing (Commonwealth), Department of Human Services (Victoria), Department of Veterans' Affairs (Commonwealth), General Practice Divisions Victoria, National Ageing Research Institute, Pharmacy Guild of Australia – Victorian Branch, Residential Care Rights Advocacy Service, Royal Australian College of General Practitioners Victoria, Royal College of Nursing Australia, Victorian Association of Health and Extended Care.

general practice has approximately doubled in the last five years[2], and nurses are an integral part of many practices' regime of administering vaccines, checking expiry dates, managing the cold chain, and reordering or replacing stock. All Division 1 Registered Nurses in Australian general practice should be able to access and administer vaccines if appropriately trained to do so and under the supervision of the general practitioner, without the need for a specific permit.

However, we understand that the permit system is mandated by the Act, and not the regulations. Therefore, our comments here are intended to help make the permit system work within general practice without imposing significant and unwarranted financial burdens on practices.

Currently, general practices requiring a permit are required to purchase a Type 29 permit – "Up to 30 beds". (It seems the system was designed primarily with hospitals in mind, not general practice). The cost for this type of permit is $547.00 for the first year and $305.00 for every subsequent year. The yearly fees do not necessarily include a visit from the Drugs and Poisons Unit. We believe that the fee structure as it applies to general practice is essentially a revenue raising exercise that clearly contravenes the principals established by the Office of Regulation Reform and the Victorian Efficiency and Competition Commission, including the guidance to the setting of fees[3] and the Principals for Good Regulation[4]. We have three reasons to support this argument, and they are detailed below.

Firstly, the fee structure is inequitable. For example, the fee paid by a region of the Department of Human Services to cover a chain of public hospitals would be $888 for the first year plus $419 for every subsequent year (a Type 29 permit). However, every legal entity operating a general practice service (the vast majority run a general practice service on just one campus) is required to pay between 65 and 75 per cent of these fees. A more equitable system may charge a nominal fee per doctor or per nurse working within a practice or hospital – for example, the cost of a single site visit in the first year, and $20 per doctor or nurse for every subsequent year. For example, in 2004-5 Southern Health's funding from the state government will be $455 million[5] and based on past financial figures it can expect to receive approximately an additional fifteen percent revenue from other sources[6], taking approximate revenue to $523 million. A permit for Southern Health would cover its five public hospitals and nine community health centres for a cost of $888 for the first year and $419 for every subsequent year. In contrast, the average general practitioner can expect to earn revenue from public and private sources of approximately $260,000, around half of which is then spent on staff salaries, insurance, infrastructure and business compliance costs (indeed, the Productivity Commission[7] estimates that five percent of GP earnings are already spent to comply with Commonwealth regulations and programs, and recommends that the Commonwealth work to reduce these costs). To use an extreme example: that a solo general practitioner relying on his or her nurse to access, manage and administer Schedule 4 vaccines

[2] Porritt, Julie. 2004. *National Practice Nurse Workforce Survey 2003*. Australian Divisions of General Practice. http://www.adgp.com.au/client_images/12143.pdf

[3] http://www.vcec.vic.gov.au/CA256EAF001C7B21/WebObj/BFMG-21SettingFeesandCharges/$File/BFMG-21%20Setting%20Fees%20and%20Charges.pdf

[4]http://www.vcec.vic.gov.au/CA256EAF001C7B21/WebObj/principlesofgoodregulation/$File/principles%20of%20good%20regulation.pdf

[5] Minister for Health (Victoria). "$53.5m more in massive budget boost for Southern Health". Media release, 12 July 2004.

[6] Southern Health. 2002. "Southern Health Financial Statements 2001-02". www.southernhealth.org.au

[7] Productivity Commission. 2003. *General Practice Administration and Compliance Costs*. Research Report. Canberra. www.pc.gov.au/study/gpcompliance/finalreport/

should have to pay 65 to 75 percent of the costs that Southern Health pays for a Health Services Permit clearly demonstrates that the fee structure is inequitable. It is imperative that the range of compliance costs imposed on general practice are taken into account by all agencies when setting fees. As the Productivity Commission notes, "even if the GP administrative costs associated with an individual program might be considered small, the cumulative impact of all programs can be large. This appears to have led to frustration among GPs"[8].

Secondly, if we follow a "user pays" argument, facilities should only be charged a fee in subsequent years of holding a health services permit if they are actually receiving a service from the Drugs and Poisons Unit. It is in no way clear how paying $305 every year to hold a permit pays for a service when general practices themselves derive little if any benefits from the paying of such a fee. In short, the fee structure has not been demonstrably justified.

Thirdly, the VCEC guide to the setting of fees and charges states that

> Regulatory activity is intended to elicit a particular behaviour and generally produces some form of public benefit. It is therefore not appropriate to recover the full cost of compliance where the benefits / costs of the activity are not fully restricted to the person being charged the fee. This form of fee-setting may involve consideration of the level of benefit captured by the firm versus the user/customer of the activity (pp3).

We believe that the aim of a Health Services permit is to set in place a regulatory structure to protect the public from harm associated with drugs and poisons (as stated in the Act). The benefit accrues to the public, not to the provider of the service – therefore according to VCEC principles, it is not appropriate to recover the full cost of compliance to a permit even if the Drugs and Poisons Unit can demonstrably justify that the fee structure covers the cost of compliance activities within the DPU.

Therefore we recommend a complete review of the way that fees and charges for a Health Services Permit have been set; a justification of the levels of charge as they apply to general practices in relation to other, much larger health services; and a commitment to the principles laid out by the Victorian Competition and Efficiency Commission.

Conclusion

Both the RACGP and GPDV are committed to working with the Department of Human Services to help improve the quality of general practice services and to protect the public from harm. We ask that the Drugs and Poisons Unit take into account our suggestions above when redrafting the regulations.

[8] Productivity Commission. *op. cit.* pp 82.