

## Senate Select Committee on Red Tape

### *Inquiry into the effect of red tape on pharmacy rules*

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## Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Senate Select Committee on Red Tape's Inquiry into the effect of red tape on pharmacy rules.

## About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 30,000 pharmacists<sup>1</sup> working in all sectors and locations.

PSA's core functions include:

- providing high quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

## Background

PSA understands the committee is inquiring into and reporting on the effect of restrictions and prohibitions on business (red tape) on the economy and community, with particular reference to:

- a) the effects on compliance costs (in hours and money), economic output, employment and government revenue, with particular attention to industries, such as mining, manufacturing, tourism and agriculture, and small business
- b) any specific areas of red tape that are particularly burdensome, complex, redundant or duplicated across jurisdictions

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<sup>1</sup> Pharmacy Board of Australia. Registrant data. Reporting period: 1 Apr 2017 – 30 Jun 2017. At: [www.pharmacyboard.gov.au/About/Statistics.aspx](http://www.pharmacyboard.gov.au/About/Statistics.aspx)

- c) the impact on health, safety and economic opportunity, particularly for the low-skilled and disadvantaged
- d) the effectiveness of the Abbott, Turnbull and previous governments' efforts to reduce red tape
- e) the adequacy of current institutional structures (such as Regulation Impact Statements, the Office of Best Practice Regulation and red tape repeal days) for achieving genuine and permanent reductions to red tape
- f) alternative institutional arrangements to reduce red tape, including providing subsidies or tax concessions to businesses to achieve outcomes currently achieved through regulation
- g) how different jurisdictions in Australia and internationally have attempted to reduce red tape, and
- h) any related matters.

PSA's submission is in response to the committee's specific focus on "pharmacy rules". PSA has received advice through the committee secretariat that, for the purpose of this inquiry, 'all red tape issues in trying to establish and run a pharmacy' will be covered.

## Summary

*The Pharmaceutical Society of Australia (PSA) provides the following recommendations to the Inquiry into the effect of red tape on pharmacy rules.*

1. *The Pharmaceutical Benefits Scheme (PBS) Safety Net arrangements require urgent reform in relation the archaic nature of manual recording, the significant administrative burden on pharmacists and the inconvenience experienced by patients and families who require regular medication for chronic conditions. PSA recommends the establishment by Government of a centrally administered system, similar to the Medicare Safety Net system which is already in place. Such a system would be expected to allow pharmacists to focus on delivery of timely professional care by removing distractions imposed by administrative tasks. Patients and families who rely on the PBS Safety Net arrangement will also see a more efficient and equitable system to support their medication needs.*
2. *Although the PBS authority system primarily affects prescribers, some aspects have flow-on effects on pharmacists' practice and patient care. PSA believes there is scope for improvement with both categories of the PBS authority prescription system.*
3. *The lack of uniformity of medicines legislation across states and territories impact negatively on pharmacists' practice and patient care. PSA strongly recommends that work in this area be progressed by Government to commence design and consultation on a model for implementation.*
4. *PSA supports the move towards a truly paperless system of electronic prescribing and electronic prescriptions. This is likely to contribute to a more efficient healthcare system as well as enhanced medication safety and quality use of medicines for patients and families.*

## Issues identified

This section provides examples of restrictions or prohibitions on business (red tape) that pharmacists encounter and the resulting impact on the economy and community.

### 1. Pharmaceutical Benefits Scheme (PBS) Safety Net arrangements

The dispensing of PBS (and RPBS) medicines is a core professional activity for pharmacists and a significant component in the operation of a pharmacy.

The PBS Safety Net is designed to help individuals and families with chronic conditions (and a reliance on medication use) by protecting them from the cost of the large number of PBS (and RPBS) medicines they may need. Once the total contribution of pharmaceutical costs by a patient reaches an annual threshold amount, the cost of medicines is reduced (or become free of charge) for the remainder of the calendar year.

#### *Administrative burden on pharmacists*

Although patients are responsible for maintenance and storage of their Prescription Record Form (PRF) which documents eligible benefits of the supply of PBS medicines, there is significant reliance on pharmacists to operationalise the Safety Net arrangements since, on request by patients, pharmacists are required to record the supply of items on the PRF.

The following outlines typical experiences of pharmacists as well as feedback received from patients and families.

- The PRFs are made available at pharmacies and this immediately creates a very large administrative burden on pharmacists who need to maintain supplies of PRFs and other paperwork, and assist patients and families with maintaining or completing PRFs or navigating through associated issues. This arrangement also creates an expectation for patients that a pharmacy is where PBS Safety Net queries and problems can be addressed.
- The amount that can be counted towards the Safety Net can be different to the total amount paid by the patient since some costs (e.g. brand premiums, special patient contributions) cannot be included. Items dispensed through PBS early supply provisions are also not eligible for Safety Net benefits. Patients often find these intricacies difficult to understand and it can be time consuming for pharmacists to provide an explanation that is satisfactory from the patient's perspective.
- When a patient loses a PRF, a pharmacist will invariably prepare a duplicate copy when requested even though under PBS rules there is no obligation to do so. This type of activity should be handled by Medicare Australia.
- Having to post in hardcopies of paperwork is archaic and pharmacists also encounter instances when they are lost in the post or apparently mislaid by Medicare Australia. Pharmacists are then responsible for additional work to correct the paper trail.

For pharmacists, the Safety Net arrangement is an administrative burden that distracts them from their professional responsibilities and impacts on the timeliness of care they provide to patients. As outlined above, the experience for patients and families could also be improved.

### ***Urgent need for a centralised electronic system***

The requirement for manual recording of the supply of pharmaceutical items is one of the most archaic features of the Safety Net arrangement and a constant source of frustration for pharmacists.

Pharmacists have been disappointed for decades that, despite information and data on PBS medicines dispensed being recorded electronically and captured by Medicare Australia, progress has not been made with regards to Safety Net arrangements. In addition, given a centralised arrangement operates for the Medicare Safety Net, pharmacists find it difficult to comprehend why the PBS Safety Net could not operate in a similar manner.

Specific examples of how the current lack of a centralised system impacts on pharmacists as well as patients and families include the following.

- As patients can have their medicines dispensed at any pharmacy, keeping track of an up-to-date Safety Net record can be a challenge since their dispensing records are not centralised and they may not have their PRF with them at all times. Patients often assume that any pharmacy can access all of their PBS dispensing history. At times they express disbelief that this is not the case and often annoyance with the inconvenience of having to track down historical information from multiple pharmacies.
- Enquiring about family dynamics and arrangements for determining Safety Net entitlements can be difficult, burdensome and sometimes seen as intrusive by patients. Pharmacists should not be tasked with this role. A centralised system, similar to the Medicare Safety Net, which automatically links eligible family members is seen as a priority for pharmacists.
- The Safety Net accommodates cross-over arrangements where a patient may have varying entitlement status (general patient or concessional patient) during the calendar year. Again this can result in additional administrative burden for everyone that could be eliminated through a centralised system.
- If a patient spends over the threshold amount before receiving their PBS Safety Net Card, they may be able to get a refund from the Department of Human Services. This requires pharmacists to provide details of the supply and a signed statement even though they are not responsible for issuing any refunds. Although this ensures patients are not disadvantaged financially, this type of arrangement would not be necessary if a centralised system was in place to trigger the eligibility for a card as soon as the patient/family reaches their threshold amount.

### ***Flow-on impact of PBS authority system on Safety Net benefits for patients***

Under the PBS, a prescriber can write authority prescriptions. Currently there are two categories of authority required benefits – *Authority required* (which requires prior approval via post, telephone or web site) and *Authority required (STREAMLINED)* (which requires inclusion of a streamlined authority code on the prescription but does not require prior approval from the Department of Human Services).

For items listed on the PBS, there is a maximum quantity (generally intended to provide one months' therapy) and maximum number of repeats specified. A prescriber may determine that a patient requires larger quantities for their therapy. In this case, the prescriber must obtain prior approval (i.e. it cannot be a streamlined authority prescription).

In some cases, the prescriber may not have applied for a prior approval authority, for whatever reason – in which case the patient requiring a higher dose may run out of their medication before the 20 days have lapsed when they can receive a further supply. Although the Safety Net early supply rule may be able to be applied for the particular medicine, payment for this supply will not count towards the Safety Net threshold. This can impact on the patient financially or may disrupt continuity of therapy. Pharmacists also face a difficult situation where patients perceive the pharmacists are denying them of the medication they need.

PSA acknowledges that the main red tape issue here relates to the prescriber's inability to use the streamlined authority option for patients with a different therapeutic requirement. However, this represents a reasonably typical scenario where the flow-on effects impact on pharmacists' practice and patient care.

A second issue relates to the *Authority required (STREAMLINED)* category. A predetermined four-digit streamlined authority code applies to each restriction for a streamlined authority item. This number must be included on the authority prescription by the prescriber. From time to time, the code is changed or reassigned by Medicare Australia. If the prescriber is unaware of this or has not assigned the correct (new) code, the authority prescription will be rejected at the point of dispensing. As the code relates to the patient's health circumstance and the prescribing decision, pharmacists are not in a position to determine the correct code. This requires the dispensing pharmacist to follow up with the prescriber to obtain or confirm the correct code.

Once again, PSA acknowledges this relates to a red tape issue at the prescriber's end. However, the outcome is that pharmacists are faced with an administrative burden which impacts unnecessarily on professional practice and patients are also inconvenienced.

## **2. Lack of uniformity of medicines legislation across states and territories**

Since July 2010, health practitioners have been registered nationally with the establishment of the Australian Health Practitioner Regulation Agency. This has enabled pharmacists (and other registrable health practitioners) to be able to practise anywhere in Australia with a single registration process. (Prior to this time, pharmacists were required to be registered by each registering authority in the jurisdiction in which they practised.)

In the context of pharmacy practice, 'running a pharmacy' includes the ability of pharmacists to practise efficiently and effectively with regards to the handling and management of medicines. As custodians of all medicines, pharmacists regard having uniform national rules for medicines to be a priority issue to remove duplication and confusion for patients and families, and enhance quality use of medicines.

PSA is aware that there has been general support expressed by most, if not all, stakeholders to have national uniformity of drugs and poisons legislation but understand there has not been adequate design of, or consultation on, a model for implementation.

PSA was particularly encouraged that the Standing Council on Health had reportedly touched on ways to improve national coordination and oversight to achieve an effective and efficient system including the adoption of nationally uniform regulatory controls for poisons.<sup>2</sup> PSA strongly believes that, in the context of the Poisons Standard (*Standard for the Uniform Scheduling of*

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<sup>2</sup> Standing Council on Health. Communiqué. 10 Aug 2012. At: [www.health.gov.au/internet/main/publishing.nsf/Content/E6428A1A8851C26FCA257BF0001B745A/\\$File/120810.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/E6428A1A8851C26FCA257BF0001B745A/$File/120810.pdf)

*Medicines and Poisons*), consideration of the national uniformity approach could also logically be extended to medicines.

### 3. Electronic prescriptions

PSA supports the move towards electronic prescribing and electronic prescriptions to an extent where Australia can claim to have a truly paperless system. This is in the interests of patient safety and timely care, workflow efficiencies for prescribers and pharmacists, and reduction in risk of errors. It is expected that patients and families will also experience convenience and better medication management overall.

The interim report<sup>3</sup> of the Review of Pharmacy Remuneration and Regulation cited Norway, Sweden, Canada and Finland as examples of successful implementation of electronic prescription systems with near universal uptake.

## Summary

Pharmacists are health professionals with a strong focus on delivering high quality services, timely patient care and the best possible health outcome for patients and the community. Any reduction in, or elimination of, red tape will assist in enhancing efficiency and timeliness for pharmacists' practice and, consequently, patients' health needs can be better supported.

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<sup>3</sup> Review of pharmacy remuneration and regulation, Interim report, Jun 2017. At: [www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/\\$File/interim-report-final.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/interim-report-final.pdf)