
PHARMACY REGISTRATION BOARD OF WESTERN AUSTRALIA

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Communiqué

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In this issue we discuss:

- ❖ Registration Renewal Statutory Declarations
- ❖ Mandatory Reference Documents
- ❖ Storage of Prescription Records
- ❖ Non PBS Pharmacies Dispensing PBS Medicines

Registration Renewal Statutory Declarations

Following renewal of registrations of pharmacy premises to 30 June 2016, the Board draws the attention of pharmacists with overall responsibility for the pharmacy business carried on at pharmacies (*Responsible Pharmacists*) to the following matters.

- Remember, when you make a *Registration Renewal Statutory Declaration*, you are declaring that the statements in it are true.
- Be aware that in 2015, twenty *Registration Renewal Statutory Declarations* were not processed because all statements were not supported on audit.
- Ask around, it can be very stressful if the outcome of an audit requires you to make further application to renew registration within a restricted timeframe (prior to 30 June), particularly if you are overseas.
- Be responsible, ensure your registered premises complies with all the requirements of the legislation covered in the Pharmacy Act 2010 at all times.

Mandatory Reference Documents

The Board reminds all *Responsible Pharmacists* of their responsibility under *Schedule 1 of the Pharmacy Regulations 2010*, the minimum standards of fitness for the competent and safe practice of pharmacy (the Minimum Standards), to ensure that the pharmacy premises have a copy of, or immediate electronic access to, the latest editions of mandatory reference documents, and all published amendments or supplements to those editions. The link to the Minimum Standards is found below:

<http://pharmacyboardwa.com.au/uploads/Main/Schedule1MinStandards.pdf>

The Board's Inspection Program continues to show that many registered pharmacy premises do not have access to the latest editions of all mandatory reference documents because *Responsible Pharmacists* do not have procedures in place to ensure that:

- each reference document is replaced when a new edition is released; and/or
- pharmacists know how to access electronic reference documents.

By way of examples, the 2015 edition of the Australian Medicines Handbook (AMH 2015) and the 23rd edition of the Australian Pharmaceutical Formulary and Handbook (APF23) were released in January and February respectively. However, audits of *Registration Renewal Statutory Declarations* made by *Responsible Pharmacists* at six metropolitan and 15 regional pharmacies, carried out in conjunction with inspections conducted in May and June, showed that five of the 21 pharmacy premises did not have access to the AMH 2015 and 14 did not have access to the APF23.

Furthermore, the Board refers *Responsible Pharmacists* to recent communications from the Pharmacy Board of Australia and the Pharmaceutical Society of Australia regarding Cautionary Advisory Labels (CAL) which include the following advice.

- The CAL recommendations in the latest edition of the APF23 should be followed.
- Pharmacists should not rely on dispensing software CAL recommendations as errors may pose significant risks to patient outcomes.
- Pharmacists who fail to provide correct and required information about dispensed medicines may face legal sanctions.
- Pharmacists are advised to confirm that their dispensing software CAL match the APF23 CAL recommendations.

The Board supports the above advice, reiterates the potential for serious implications if pharmacists access out of date reference documents and strongly recommends that all *Responsible Pharmacists*:

- use the above link to conduct a self-audit of the Minimum Standards and address any matter of non-compliance;
- put measures in place to ensure that all mandatory reference documents are replaced when a new edition is released;
- ensure all pharmacists know how to access electronic reference documents; and
- implement a regular self-audit to promote compliance with the Minimum Standards at all times.

Storage of Prescription Records

The Board understands from the *Poisons Regulations 1965* that:

- the details of all prescriptions dispensed at, or from, a pharmacy are required to be entered into the Prescription Book;
- the entry must include a unique identifying letter or number or combination of letter and number, generally known as the prescription number;
- the Prescription Book may be in the form of computer records on disk or tape that can be displayed and from which printed copies of the records can be produced on demand.

Based on the above information, the Board considers that a record of a prescription dispensed at, or from, a pharmacy may be an electronic record. Therefore, in the opinion of the Board, if electronic records of all prescriptions dispensed at, or from, the pharmacy are:

- kept at the pharmacy in a safe and secure location; and
- dealt with in a confidential manner; and
- retained at the pharmacy for the required period of time (24 months for Schedule 4 and seven years for Schedule 8);

then *Responsible Pharmacists* are meeting their responsibilities under the *Pharmacy Regulations 2010*.

Non PBS Pharmacies Dispensing PBS Medicines

On 1 December 2014 amendments made to the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007* came into effect.

The new condition clearly states that an approved pharmacist **must not** make claim for payment for the supply of a pharmaceutical benefit unless the pharmaceutical benefit was supplied at or from the pharmacist's approved premises, thus closing any loopholes.

Any concerns regarding this issue should be lodged directly with the Department of Human Services.

The Board draws *Responsible Pharmacists* attention to its *Guidelines* regarding pharmacies that do not supply pharmaceutical benefits and advises that the messages regarding unapproved pharmacies are endorsed by the Pharmacy Board of Australia, Medicare and the pharmacy approval authorities in each State or Territory.

Pharmacies that do not supply pharmaceutical benefits

The public is entitled to know if a pharmacy is not approved to supply pharmaceutical benefits.

There should be a prominent sign displaying the following information:

This pharmacy cannot supply medicines subsidised under the Pharmaceutical Benefits Scheme (PBS).

What this means for you

Any medicines you have dispensed at this pharmacy will not be subsidised under the PBS.

Pharmaceutical Benefits Scheme (PBS) Safety Net

The cost of your prescriptions that you have dispensed here today cannot count towards your family's Pharmaceutical Benefits Scheme (PBS) Safety Net.

Impact on your repeats

Having your medicines dispensed here today will prevent you from having any further repeats of this prescription subsidised under the Pharmaceutical Benefits Scheme (PBS) at any pharmacy.

For further information

- *Ask your pharmacist*
- *Contact the Department of Health and Ageing PBS Information Line telephone 1800 020 613 Monday to Friday from 8.30 a.m. to 5.00 p.m. (AEST), or via email at pbs@health.gov.au*
- *If you have a complaint, contact AHPRA (the Australian Health Practitioners Regulation Agency) on 1300 419 495 and ask to speak to a Notifications Officer in your state or territory.*

Persons presenting prescriptions at the pharmacy are to be directed to this signage and have the financial consequences of not obtaining the medicine as a pharmaceutical benefit explained to them.

Important Information

The Board has an expectation that all *Responsible Pharmacists* comply with the requirements of the Pharmacy Act 2010 at all times and provides Communiqués to assist them to meet these responsibilities.

John Harvey

Presiding Member