# FREQUENTLY ASKED QUESTIONS

## AMENDMENTS TO THE CONDITIONS OF APPROVAL FOR APPROVED PHARMACISTS

**Question: What are the amendments to the Conditions of Approval?**

The amendments to the Conditions of Approval Determination:

1. Introduce a new condition of approval which reinforces the existing obligation of approved pharmacists to only claim reimbursement from the Commonwealth for PBS medicines which were supplied at or from approved pharmacy premises; and
2. Update the references to the Pharmaceutical Society of Australia’s relevant Codes and Standards documents with which approved pharmacists need to comply.

The new condition does not introduce any additional requirements; it simply reinforces existing provisions within the *National Health Act 1953* with regard to the supply and claiming of medicines through the Pharmaceutical Benefits Scheme.

**Question: In simple terms what does the new condition mean?**

The new condition clearly states that an approved pharmacist must not make a claim on the Commonwealth for payment for the supply of a pharmaceutical benefit (PBS medicine) unless the pharmaceutical benefit was supplied at or from the pharmacist’s approved premises.

Without limiting the above, the new condition further provides that an approved pharmacist must not make a claim on the Commonwealth for payment for the supply of a PBS medicine pharmaceutical benefit if:

* the pharmaceutical benefit was never at the approved premises; or
* a prescription for the pharmaceutical benefit was not seen, and the pharmaceutical benefit dispensed, at the approved premises.

**Question: Has there been previous communication about this requirement?**

The Department of Health, in conjunction with the Pharmacy Board of Australia, the Pharmacy Guild of Australia and the Department of Human Services, has undertaken a number of activities to educate pharmacists of their obligations under the *National Health Act 1953* (the Act).

In particular, a fact sheet was developed by the Department and distributed in a communique by the Pharmacy Board of Australia on 10 July 2012. The Pharmacy Guild of Australia released a position statement on unapproved pharmacies in relation to the supply of PBS medicines in November 2011.

In September 2014, the Department of Health wrote to all approved pharmacists regarding the proposed amendments to the Conditions of Approval.

**Question: What other changes are being made to the Conditions of Approval?**

The previous Conditions of Approval required approved pharmacists to comply with outdated versions of the Pharmaceutical Society of Australia’s Code of Professional Conduct, Professional Practice Standards and Competency Standards for Pharmacists in Australia.

The Pharmaceutical Society of Australia has updated these documents and the amended Determination requires approved pharmacists to comply with the:

* Code of Ethics for Pharmacists 2011;
* Professional Practice Standards 2010; and
* National Competency Standards Framework for Pharmacists in Australia 2010.

Copies of these publications can be found on the [Pharmaceutical Society of Australia’s website](http://www.psa.org.au/).

**Question: As a consumer, how can I tell if my pharmacy is approved to supply PBS medicines?**

Following a meeting of the Pharmacy Board of Australia on 28 January 2011, the Board advised all pharmacists that unapproved pharmacies must display signage so consumers can identify the pharmacy is not approved to dispense PBS medicines.

While the vast majority of pharmacies operating in Australia are approved by the Government to supply PBS medicines, there are a small number of pharmacies that do not have this approval.

Pharmacies which are not approved to supply PBS medicines are still registered in each state or territory to supply any prescription at full price. Any prescriptions supplied by an unapproved pharmacy are private (non-PBS) supplies and do not count towards the patient’s PBS safety net.

If in doubt, you can ask at the pharmacy.

**Question: What type of existing supply arrangements will be affected by these changes?**

All supplies made through a community pharmacy that is approved under section 90 or 90A of the Act will be subject the revised Conditions of Approval. These pharmacies can supply PBS medicines to patients presenting to the pharmacy with a PBS prescription, to Residential Aged Care Facilities and, in some cases to patients receiving treatment in or at hospitals, including those receiving chemotherapy.

Pharmacists should be aware that these are not new requirements. The Act currently states that an approved pharmacist can only claim for the supply of a pharmaceutical benefit at or from premises for which they have been approved.

The Conditions of Approval do not apply to supplies made through section 94 hospital pharmacies.

**Question: Can I claim for the supply of a pharmaceutical benefit if the stock is owned by and dispensed at another pharmacy that is not approved for PBS purposes?**

No, pharmaceutical benefits may only be supplied and claimed by an approved pharmacy. The new Condition of Approval reinforces and clarifies the requirements of the *National Health Act 1953* by specifying that the:

* claim for payment can only be made if the supply was made at or from an approved pharmacy;
* pharmaceutical benefit must have been at the approved premises;
* pharmacist, or their agent, at the approved premises must have seen the prescription for the benefit; and
* pharmaceutical benefit must have been dispensed at the approved premises by the pharmacist, or their agent.

**Question: Can I claim for a supply where the prescription is transferred to my approved pharmacy, from premises which are not approved, prior to the pharmaceutical benefit being dispensed at my approved premises?**

Yes, both the Act and the Conditions of Approval allow these types of supplies to be claimed. So long as the pharmaceutical benefit is at your approved premises and the dispensing of the benefit is completed at the approved premises, supported by a prescription which is sighted by a pharmacist at the approved premises prior to dispensing, a claim will be considered valid.

**Question: Can I claim for supplies made through a pharmacy depot?**

Yes, the new condition of approval will not impact supply arrangements that currently occur through depot or agency arrangements. Pharmacists must ensure that in making a supply under such arrangements that they continue to meet their obligations under the conditions of approval including that the:

* claim for payment can only be made if the supply was made at or from an approved pharmacy;
* pharmaceutical benefit must have been at the approved premises;
* pharmacist, or their agent, at the approved premises must have seen the prescription for the benefit; and
* pharmaceutical benefit must have been dispensed at the approved premises by the pharmacist, or their agent.

**Question: Will supplies to patients in residential aged care facilities be affected?**

No, supplies to residential aged care facilities will not be affected. However, in making the supply pharmacists will need to ensure they are compliant with the requirements of both the Act and the Conditions of Approval.

**Question: My pharmacy supplies the local hospital, how will these supplies be affected?**

While any supply that you make to a hospital will be unaffected by the new condition, as an approved pharmacist, you are required to ensure you comply with the requirements of both the Act and the Conditions of Approval. Pharmacists should note that some supplies to public hospital patients are not eligible for PBS subsidy.

**Question: How will supplies under Section 100 arrangements be affected?**

All supplies made under section 100 arrangements through an approved pharmacy are subject to the new arrangements. However, it is necessary that limited exceptions apply for some programmes.

For the Highly Specialised Drugs and Efficient Funding of Chemotherapy programmes, pharmacists are exempt from complying with the new condition of approval when supplying infusion medications that, once prepared for use, have a physical, chemical or biological stability that restricts the clinically effective shelf life period to **8 hours or less**. In such circumstancespharmacists will not need to comply with the new condition of approval.

In these circumstances, it is not always practical for the pharmaceutical benefit to have been at the approved premises. Exemption provisions are provided for within the legislative instruments for each relevant programme to exclude pharmacists from complying with the new condition when dispensing infusions that, once prepared, have a shelf life of 8 hours or less. For these medications, usual supply arrangements can continue to occur and the claim may be submitted without the pharmaceutical benefit having been at the approved premises.

An exemption for compliance with new subsection 8(3), that the pharmacist must have seen the prescription and the dispense of the benefit to have occurred at the approved premises, also applies for those supplies made to Aboriginal Health Services through the Remote Aboriginal Health Services Programme.

For the supply to Aboriginal Health Services through the Remote Aboriginal Health Services Programme, pharmacists still need to ensure that they meet the requirements of subsections 8(1) and 8(2). That is, the pharmaceutical benefit must have been at the approved premises before a claim for its supply can be made.

**Question: I dispense some infusion medicines under the Highly Specialised Drugs and Efficient Funding of Chemotherapy programmes which have short shelf-lives. How can I comply with the new condition for these medicines?**

The Department recognises that once prepared for use, some infusion medicines have a reduced shelf-life limiting the physical, chemical or biological stability of the drug. Some of these medicines are prepared offsite from the approved pharmacy, for example by a third party compounder. For these medicines it is not practical that they be prepared, returned to the pharmacy and then provided for administration to the patient.

For medications with an effective shelf-life of 8 hours or less, existing supply arrangements can continue to occur and the claim may be submitted without the pharmaceutical benefit having been at your approved premises.

A specific exemption within the legislative instruments for both programmes has been introduced to exclude pharmacists from complying with the new condition when dispensing infusions that, once prepared, have a shelf life of 8 hours or less.

**Question: What other exemptions exist in relation to the new condition?**

In some limited circumstances the supply of PBS medicines can occur without the presence of a PBS prescription. These circumstances include the dispensing of medications for doctors bag supplies and under continued dispensing arrangements. For these types of supplies, subsection 8(3)(a), requiring that the pharmacist has seen the prescription, do not apply.

The Act also allows that, in the circumstance of an existing approved pharmacy relocating to new premises, the pharmacy may be entitled to claim for 90% of the supply of pharmaceutical benefits from the new (unapproved) premises prior to the relocation being approved. Such claims for supply of PBS medicines made from the new premises prior to the granting of approval are not subject to the new condition of approval.

**Question: Do the Conditions of Approval apply to Section 94 hospital pharmacies?**

No, the Conditions of Approval only apply to those pharmacists approved under section 90 or 90A of the Act.

**Question: Will an unapproved pharmacy be prevented from supplying private prescriptions and over the counter medicines?**

No, the amendments do not preclude the operation of unapproved pharmacies from supplying non-PBS medicines (private prescriptions), over the counter medicines, nor acting as a recognised collection and distribution point for PBS medicines.

**Question: What are the consequences for non-compliance with the Conditions of Approval?**

Where a breach of the Conditions of Approval (new and existing) has been deemed to occur, the *National Health Act 1953* provides that the following compliance measures can be undertaken:

* recovery of monies (sections 99AA and 99AB of the Act); and
* reprimand, suspension or revocation of approval, following an inquiry by a Pharmaceutical Services Committee of Inquiry (section 95 of the Act); and/or
* prosecution for a criminal offence under the Act or *Criminal Code.*

**Question: What is the role of the Pharmaceutical Services Committee of Inquiry?**

Where there is evidence of a breach of the Conditions of Approval, the Secretary of the Department of Health or the Minister for Health may refer the matter to the Pharmaceutical Services Committee of Inquiry for investigation.

The Committee of Inquiry has the power under the Act to investigate suspected abuse of the conditions of approval to supply PBS medicines. The committee is able to summons witnesses to appear and produce evidence as part of its investigation.

The committee provides a report to the Minister for Health with a series of recommendations. Based on this report, the Minister may choose to reprimand an approved pharmacist, suspend or revoke the approval of the pharmacist under Part VII of the Act or take no action.

**Question: Where can I find copies of the relevant legislation?**

The two pieces of legislation discussed in these Frequently Asked Questions are the [*National Health Act 1953*](http://www.comlaw.gov.au/Details/C2014C00353) and the [*National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007*](http://www.comlaw.gov.au/Details/F2007L02703)*.*

Copies of the legislation are publicly available from [ComLaw](http://www.comlaw.gov.au/Details/C2014C00353).

**Question: When do these changes come into effect?**

The amended conditions of approval take effect from 1 December 2014. This follows the public consultation process conducted in September and October 2014.

**Question: What if I have concern or questions about the Conditions of Approval?**

You can contact the Department in writing by emailing pharmacyconditions@health.gov.au.