

Consultation paper

Pharmacy Regulation: ongoing regulation of pharmacy ownership and registration of pharmacy business premises in Tasmania.

A copy of the Consultation Paper is available online at <http://www.dhhs.tas.gov.au>

A copy of the Inter-Governmental Agreement relating to the project is available online at www.nhwt.gov.au/natreg.asp.

A copy of the *Pharmacists Registration Act 2001* is available online at www.thelaw.tas.gov.au.

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The closing date for return of submissions is:

close of business on Friday, 16 October 2009

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I. Purpose of this paper

This consultation paper seeks feedback on how the regulation functions associated with the regulation of pharmacy ownership and registration of pharmacy business premises will be continued in Tasmania following the commencement of the National Registration and Accreditation Scheme for Health Professions (the national scheme) on 1 July 2010. This paper proposes a model to enable those functions to continue.

The consultation paper provides an opportunity for stakeholders and the general public to provide comments in relation to the proposal. Comments received will inform the Tasmanian Government's development of policy for the ownership and regulation of pharmacy business premises.

The paper has been developed by the Department of Health and Human Services and the Pharmacy Board of Tasmania.

2. Introduction

The Council of Australian Governments (COAG) at its meeting of 14 July 2006, agreed to establish a single national registration scheme for health professionals. Responsibility for implementation of the national scheme passed to Health Ministers with the signing of an Inter-Governmental Agreement on 26 March 2008. Health Ministers have agreed that the national scheme will be fully operational by July 2010.

The new national scheme will, for the first time, create a single national registration and accreditation system for 10 health professions, including the pharmacy profession.

The structure and functions of the national scheme are to be set out in legislation. Queensland is to host the substantive legislation (Bill B) and the other jurisdictions are to adopt and apply that model in their own legislation (Bill C) in order to enter the national scheme.

On the 25 November 2008, the first piece of legislation to establish the national scheme, the *Health Practitioner Regulation (Administrative Arrangements) National Law Act 2008* (Bill A), received Royal Assent in Queensland. The Act enables the Ministers to appoint the Agency Management Committee, National Boards and the Advisory Council. The Act enables the new national health profession boards, including the Pharmacy Board of Australia to be established.

Bill B will restate the provisions of Bill A and will establish the scheme and prescribe registration and accreditation arrangements, complaints and enforcement arrangements, privacy and information-sharing arrangements, as well as other matters.

Tasmania's Bill C will adopt the national law as set out in Bill B as the law of Tasmania and will include various savings, transitional and consequential amendments.

In relation to pharmacy regulation, section 1.33 of the Inter-Governmental Agreement states that '[t]his Agreement does not cover the licensing of pharmacy premises and pharmacy ownership restrictions. These matters will continue to be the responsibility of the States and Territories'. Therefore under the national scheme the Pharmacy Board of Australia will **not** have responsibility for the regulation of pharmacy ownership and registration of pharmacy business premises. The Pharmacy Board of Australia will register individual pharmacists, approve the accreditation standards for courses leading to national registration as a pharmacist and manage the complaints and disciplinary process.

The matter arising from the Inter-Governmental Agreement is how the regulation of pharmacy ownership and registration of pharmacy business premises will be administered post 1 July 2010 under state and territory legislation.

This consultation paper proposes a model for the regulation of pharmacy ownership and registration of pharmacy business premises in Tasmania after 1 July 2010.

3. Current arrangements

The ownership arrangements of pharmacy businesses currently vary between states and territories. All states and territories, including Tasmania, have enacted legislation that places restrictions on the ownership of pharmacy businesses. Appendix I summarises state and territory laws in this area and shows that approving those who can conduct a pharmacy business is managed in different ways across Australia.

In Tasmania, regulation of pharmacy ownership and registration of pharmacy business premises is provided in the *Pharmacists Registration Act 2001* (the Act). The Act provides for the establishment of the Pharmacy Board of Tasmania, and requires them to perform certain statutory functions.

The Pharmacy Board is currently responsible for the annual registration of pharmacists. Under the national scheme, this function will transfer to a national pharmacy board.

Regulation of Pharmacy Business Premises

Under Part 6A of the Act, the Pharmacy Board is also currently responsible for registering all pharmacy business premises (other than those located within public hospitals). Part 6A of the Act is reproduced in Appendix 2. Section 71E prescribes that a fee may be charged by the Board for the registration of pharmacy business premises. This is currently set as a one-off fee of \$300 by the Regulations.

Prescribed One-off Registration of Premises Fee	\$300
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Regulation of Pharmacy Business Ownership

The Act also places restrictions on the ownership of pharmacy businesses. Section 62 provides that it is an offence for a person to hold an interest in a pharmacy business unless they are:

- a registered pharmacist
- a body corporate whose members are either registered pharmacists or family members¹ of a registered pharmacist who is also a member
- a Friendly Society.

Section 65 limits the number of pharmacies in which a registered pharmacist or a Friendly Society (whether alone, in partnership or as a member of a body corporate) may hold a direct or indirect interest to four pharmacy businesses.

Unlike the provisions in Part 6A relating to registration of pharmacy business premises, neither section 62 nor 65 impose any statutory obligation on the Pharmacy Board to assess pharmacy business ownership. In practice, the Board has taken on administrative functions of assessing a corporate provider's application to own (or part own) a pharmacy business. It levies administrative fees for performing this function as follows:

Initial Application for Approval of Corporate Provider (company only)	\$550
Initial Application for Approval of Corporate Provider (company and trust)	\$990

¹ Family members are limited to the spouse, father, mother, son, daughter, grandson, granddaughter, brother or sister of the registered pharmacist(s) [Section 62 (2)(c)]. Spouse includes the person who is in a significant relationship with the pharmacist, within the meaning of the *Relationships Act 2003*.

Annual Return of Information from Corporate Providers	\$165
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Inspections

The Act provides that the Board may appoint an inspector to inspect premises if it suspects that a registered pharmacist may be providing pharmacy services in or from inadequate or inappropriate pharmacy premises. There is currently no fee prescribed in the legislation for such an inspection.

In considering an application for registration of pharmacy business premises, the Act requires that the Board be satisfied that the premises are suitable for use as a pharmacy. Suitability is measured against the matters set out in section 71E of the Act (see Appendix 2) and by reference to the Pharmacy Code (a set of guidelines published by the Board under section 12 of the Act). In relation to pharmacy business premises, the Code provides guidance on requirements for dispensaries, counselling areas, dose administration, container packaging, unpacking and storage areas, security, equipment, public access and access to other premises.

To assess suitability for registration, the Board inspects the premises. Similarly, where renovations or alterations are to be carried out to pharmacy business premises which will affect the internal layout of the dispensary or areas where scheduled medicines are stored, the Pharmacy Board approves the work prior to commencement and the completion of the alterations. There are no legislatively prescribed fees for these inspections, however it is the practice of the board to impose an administrative fee as follows:

Premises Inspection	\$165
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4. Proposal

The proposed model seeks to amalgamate those functions that are currently performed by the Board administratively and legislatively. It has been developed to provide for minimal change from the current arrangements. It is proposed that the new legislation ratify practices that are already being performed by the Pharmacy Board with respect to pharmacy ownership and businesses in this State.

Model

It is proposed that a new Tasmanian Pharmacy Authority (TPA) be established to perform functions under the Act with respect to:

- approving interests in pharmacy businesses
- registering pharmacy business premises and
- inspecting pharmacy premises to ensure that they are being carried out in a manner that provides the public with the highest possible standard of pharmacy care.

Legislative change to establish the proposed authority

It is proposed that the existing *Pharmacists Registration Act* be amended. This is likely to be the simplest method of achieving the desired outcome.

In the transition to the national scheme, the Act will need to be amended so that those provisions covered by the National Registration and Accreditation Scheme from 1 July 2010 are repealed.

To establish and provide for the operation of the TPA, some modifications to the Act will be required. These will include:

- potentially renaming the Act to shift the focus to pharmacy businesses and premises, rather than regulating pharmacist registration
- establishing the TPA in lieu of the former Board and changing the process for the appointment of members
- providing for the annual renewal of pharmacy business premises registration and prescribe an associated fee
- providing for routine inspections, to occur no more than once every 5 calendar years
- providing clauses that deal with eligibility requirements for those proposing to own an interest in a pharmacy business
- formalising the arrangements for fees payable for approval for pharmacy business ownership and inspections of premises, where necessary, and
- other consequential amendments resulting from the operation of the national law.

Governance of the proposed authority

Members of the proposed TPA board will be appointed by the Minister. It is proposed that the TPA consist of three members comprising two registered pharmacists and one person who has never been a registered pharmacist. TPA members would be appointed for terms of three years, and may be eligible for reappointment.

Positions on the TPA would be advertised. Ministerial appointments would be made from nominations from registered pharmacists, professional associations representing the interests of

pharmacists and from the general public. Existing members of the current Pharmacy Board of Tasmania would be encouraged to apply given the relevance of their skills and experience. Further, this would provide stability in implementing the new arrangements. The chairperson would be appointed by the Minister and would be a registered pharmacist. Members of the TPA would be entitled to remuneration as determined by the Minister.

The activities of the TPA may not warrant the establishment of a dedicated administration. Instead, it is proposed that to support the operational activities of the TPA, administrative services could be provided on a contractual basis, as has long been the case with the Pharmacy Board of Tasmania.

Powers and functions

It is proposed that the TPA retain the legislative functions of the existing Board with respect to registration of pharmacy business premises. It is proposed that the TPA have the power to issue guidelines. In addition, it is proposed that the TPA be given additional legislative powers to:

- approve ownership and interests in pharmacy businesses by a corporate entity
- undertake routine inspections, approve alternations to and transfers of ownership of pharmacy business premises, and
- charge fees for these functions.

Financial provisions

The financial provisions under Part 2 Division 4 of the current Act set out the powers of the Board in relation to establishing funds, investments and setting of fees. It is proposed TPA be given similar powers.

It is proposed that the TPA operates on a 'full cost recovery' principle and that it sets appropriate fees in relation to its activities. It is proposed that all fees for the registration of premises and the assessment of ownership will be prescribed by regulation. An estimated schedule of fees to be charged by the TPA is provided in Appendix 3A. The collection of fees is expected to fund the operation of the TPA as set out in Appendix 3B.

Reporting obligations of the proposed authority

As is the case with the current Pharmacy Board, the TPA would be subject to the *Audit Act 2008*, including the requirement to prepare and table annual reports in parliament. The legislation establishing the TPA would specifically require certain matters to be included in the annual report, such as the number of approvals and ownership statistics.

Relationship with the Pharmacy Board of Australia and the Tasmanian Health Complaints Commission

It is proposed that the TPA will be able to share information with the national Board in order to ascertain the registration status of pharmacists with interests in pharmacy businesses or pharmacy business premises where appropriate. A memorandum of understanding between both authorities could be utilised to formalise these arrangements.

The TPA, like any member of the community, may make a complaint to the Pharmacy Board of Australia regarding issues that relate to the conduct or health of a registered pharmacist.

The Health Complaints Commissioner would also continue to play a role in negotiating with the relevant agency (such as the TPA in relation to an ownership or pharmacy registration matter, or

the Pharmacy Board of Australia in relation to an individual performance or conduct matter) to determine the most appropriate way of dealing with a complaint.

5. Opportunity for comment

Feedback is invited from interested organisations and individuals on the proposed model to continue the regulation of pharmacy business premises and ownership in Tasmania. Issues for comment include:

- Do you agree with the establishment of an independent statutory authority (TPA) for the purposes of pharmacy business ownership and premises regulation?
- Is the composition of the proposed authority appropriate for its proposed functions?
- Is the current range of roles and powers proposed adequate to protect the public? Are there any extra functions that the authority would require?
- Do you agree with the proposed fees?

The consultation process will run in parallel with establishing the national registration and accreditation scheme. Following consultation on this paper, advice with regard to a final model will be incorporated into the process to establish enabling legislation in Tasmania and any consequential amendments that may be necessary.

Lodgement of submissions

Written submissions may be posted, faxed or emailed to:

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Appendix I

Existing state and territory pharmacy legislation

State/territory	Legislation	Mandatory registration of pharmacy premises	Ownership restricted to pharmacists/friendly societies	Limitation on numbers of pharmacies/friendly societies
Tasmania	<i>Pharmacists Registration Act 2001</i>	Yes	Yes	Four for pharmacist owners and four for friendly society pharmacies
Queensland	<i>Pharmacists Registration Act 2001</i>	No	Yes	Five for pharmacist owners and six for friendly society pharmacies.
Victoria	<i>Health Professions Registration Act 2005</i>	Yes	Yes	Five for pharmacist owners and six for friendly society pharmacies. Friendly societies that owned more than six pharmacies at 16 November 2008 may grow by an additional 30%.
New South Wales	<i>Pharmacy Practice Act 2006</i>	Yes	Yes	Five for pharmacist owners and six for friendly society pharmacies (with ministerial approval).
Western Australia	<i>Pharmacy Act 1964</i>	Yes	Yes	Five for pharmacist owners and six for friendly society pharmacies (with ministerial approval).
South Australia	<i>Pharmacy Practice Act 2007</i>	Yes	Yes	Six for pharmacist owners and 40 for friendly society pharmacies (restricted to national pharmacies).
Northern Territory	<i>Health Practitioners Act 2007</i>	No	Yes	Unlimited for pharmacist owners and friendly societies. Friendly society pharmacies require Ministerial approval
Australian Capital Territory	<i>Health Professionals Act 2004</i>	Yes	Excludes friendly societies	Unlimited for pharmacist owners. Friendly society excluded from ownership definition.

Appendix 2

Pharmacists Registration Act 2001

PART 6A - Registration of pharmacy business premises

71A. Interpretation of Part

In this Part –

"eligible person" means any of the following:

- (a) the holder of full or interim registration as a pharmacist;
- (b) an applicant for registration as a pharmacist;
- (c) a body corporate lawfully providing, or proposing to lawfully provide, pharmacy services;
- (d) a body that is –
 - (i) lawfully permitted to call itself a Friendly Society; and
 - (ii) lawfully providing, or proposing to lawfully provide, pharmacy services;

"responsible occupier", of premises, means a person who is, for the time being, providing pharmacy services in or from those premises, other than a person who works under the control and supervision of a registered pharmacist at those premises.

71B. Application of Part

- (1) This Part does not bind the Crown.
- (2) This Part does not apply to –
 - (a) premises that are used for the purposes of a pharmacy business and are located wholly within a hospital operated by an agency or instrumentality of the Crown in right of Tasmania or the Commonwealth; or
 - (b) prescribed premises, prescribed persons or prescribed pharmacy practices or services.

71C. Pharmacy business premises to be registered

After 1 September 2006, a person must not use any premises for the purposes of a pharmacy business unless those premises are –

- (a) registered as pharmacy business premises; or
- (b) exempt, under [section 71J](#), from the requirement to be registered as pharmacy business premises.

Penalty:

Fine not exceeding 25 penalty units and, in the case of a continuing offence, a further fine not exceeding 2.5 penalty units for each day during which the offence continues.

71D. Applications for registration of pharmacy business premises

- (1) A person may apply to the Board to have premises registered as pharmacy business premises.
- (2) The application is to be –
 - (a) in an approved form; and

- (b) lodged with the Registrar; and
 - (c) accompanied by the prescribed application fee, if any; and
 - (d) accompanied by such information or evidence as the Board requires.
- (3) The Board may require the applicant to provide such further information or evidence as it considers necessary in order to consider the application.
- (4) The Board may waive all or part of the fee.

71E. Consideration of applications for registration of pharmacy business premises

- (1) The Board, after considering an application to have premises registered as pharmacy business premises, may –
- (a) approve the application; or
 - (b) refuse the application.
- (2) However, the Board must not approve the application unless it is satisfied that –
- (a) the applicant –
 - (i) is an eligible person; or
 - (ii) has, by virtue of some other status, reasonable grounds for making the application; and
 - (b) the premises sought to be registered are used, or are being made ready to be used, for the purposes of a pharmacy business; and
 - (c) the premises –
 - (i) are not located wholly or partly within a supermarket; or
 - (ii) are not capable of being entered from within a supermarket; or
 - (iii) are not capable of being used to gain entry to a supermarket; and
 - (d) in terms of the objectives set out in section 10, the premises sought to be registered are suitable, or are being made suitable, to be used for the purposes of a pharmacy business.
- (3) The matters that the Board may have regard to for the purposes of subsection (2)(d) include, but are not limited to –
- (a) the standard or proposed standard of presentation of the premises, including the external appearance and internal fittings; and
 - (b) the physical condition of the premises, and the condition of associated amenities such as lighting, ventilation and sanitation; and
 - (c) the security of the premises and, in particular, the security of dispensing and storage areas; and
 - (d) key professional requirements such as the need for –
 - (i) professional supervision of the sale and supply of medicines and drugs; and
 - (ii) customer privacy and counselling; and
 - (iii) sufficient storage for medicines and drugs; and
 - (e) whether there is or will be reasonable public access to the premises and, in particular, access for disabled persons; and

- (f) if there is or will be direct access to or from adjoining premises, the nature of the activities carried out on those adjoining premises; and
 - (g) any issues of compliance regarding State or council legislative requirements on matters such as fire safety and occupational health and safety; and
 - (h) in the case of leased premises, the terms of the lease.
- (4) For the purposes of subsection (2)(c) –
- (a) a supermarket is taken to be any large enclosed shop that primarily sells fresh and processed foods (including beverages) and where the selection of goods is organised on a self-serve basis, even though –
 - (i) customer advice may always or sometimes be available in the shop; and
 - (ii) customer service and assistance may always or sometimes be available in a part of the shop; and
 - (iii) other goods (including household goods like cleaning and kitchen products and personal care products like toiletries) may also be offered for sale in the shop; and
 - (b) a large enclosed shop that sells general merchandise (commonly known as a department store) is not taken to be a supermarket even though it may –
 - (i) contain a restaurant or café; or
 - (ii) sell specialty foods such as biscuits, confectionery and condiments.
- (5) If the Board is unsure, in respect of an application under this Part, whether or not any premises are a supermarket, it may apply to the Secretary for a ruling.
- (6) If subsection (5) applies –
- (a) the Secretary, after making such inquiries as he or she considers necessary, may, in writing, make the ruling; and
 - (b) the Board is bound by that ruling.

71F. Approval or refusal of applications

- (1) If an application to have premises registered as pharmacy business premises is approved –
 - (a) the Board is to register the premises by making an appropriate entry in the register; and
 - (b) the registration takes effect as soon as the Board has complied with paragraph (a).
- (2) The Board, as soon as practicable after registering the premises, must give the applicant notice of the approval and the date of registration together with a notice or certificate, in an approved form, in evidence of the registration.
- (3) If an application to have premises registered as pharmacy business premises is refused, the Board is to give the applicant notice of –
 - (a) the refusal; and
 - (b) the reasons for the refusal; and
 - (c) the applicant's right of appeal.

71G. Nature of registration of pharmacy business premises

- (1) The registration of pharmacy business premises remains in force, subject to any period of suspension, until it is cancelled by the Board or relinquished.
- (2) However, the Board, having regard to the objectives set out in section 10, is to periodically review the registration of pharmacy business premises.
- (3) For the avoidance of doubt, the registration of pharmacy business premises is not affected by a transfer in the ownership of the premises or of the pharmacy practice or pharmacy business conducted in or from the premises.

71H. Registration of pharmacy business premises may be cancelled or suspended

- (1) The Board may cancel or suspend the registration of premises as pharmacy business premises if it is satisfied that –
 - (a) the premises have temporarily ceased to be used for the purposes of a pharmacy business; or
 - (b) having regard to the objectives set out in section 10, and the matters set out in section 71E(3), the premises are no longer suitable to be used for the purposes of a pharmacy business.
- (2) The Board is to cancel the registration of premises as pharmacy business premises if it is satisfied that –
 - (a) the premises have been, or are about to be, demolished; or
 - (b) the premises have ceased permanently to be, or are incapable of ever again being, used for the purposes of a pharmacy business.
- (3) If the Board decides to cancel or suspend the registration of any premises as pharmacy business premises, it is to make an appropriate entry to that effect in the register and give the responsible occupier of the premises notice of –
 - (a) the cancellation or suspension; and
 - (b) the reasons for the cancellation or suspension; and
 - (c) in the case of a suspension on the ground referred to in subsection (1)(b), the actions that need to be taken to have the suspension revoked; and
 - (d) the responsible occupier's right of appeal.
- (4) The cancellation or suspension takes effect when the notice is given to the responsible occupier of the premises, or on such later date as is specified in the notice.
- (5) The Board, for any reason it considers sufficient, may revoke the suspension of the registration of premises as pharmacy business premises at any time.
- (6) If the Board decides to suspend the registration of premises as pharmacy business premises it may afford the responsible occupier of the premises an opportunity to be heard but it is not required to do so.

71I. Registration of pharmacy business premises may be relinquished

- (1) The responsible occupier of premises that are registered as pharmacy business premises may relinquish that registration at any time by –
 - (a) giving an appropriate notice to the Board; and
 - (b) returning the certificate or notice of registration to the Board.

- (2) On receiving the notice the Board is to cancel the registration of the premises by making an appropriate entry to that effect in the register.
- (3) However, the Board is not required to comply with subsection (2) if it is not satisfied that –
 - (a) the giver of the notice is the responsible occupier; and
 - (b) each other eligible person with an interest in the registration has been consulted in the matter; and
 - (c) those other persons, if any, have no objection, or no justifiable objection, to the registration being relinquished.

71J. Premises exempt from registration requirements

- (1) The Board, by instrument in writing, may exempt any premises used for the purposes of a pharmacy business from the requirement to be registered as pharmacy business premises.
- (2) An exemption may be granted on the Board's own initiative, at the written request of the Director of Public Health or on an application by or on behalf of a registered pharmacist.
- (3) An application under subsection (2) is to be –
 - (a) in an approved form; and
 - (b) lodged with the Registrar; and
 - (c) accompanied by the prescribed application fee, if any; and
 - (d) supported by such information or evidence as the Board requires.
- (4) The Board may waive all or part of the fee.
- (5) An exemption may be granted –
 - (a) for individual premises or a class of premises; and
 - (b) unconditionally or on conditions.
- (6) Without limiting subsection (5)(b), the conditions of an exemption may restrict its operation according to matters or limitations, whether as to time, circumstance or otherwise, specified in the instrument of exemption.
- (7) A registered pharmacist must not engage in the practice of pharmacy contrary to a condition of an exemption under this section.

Penalty:

Fine not exceeding 25 penalty units.

- (8) The Board may revoke an exemption if it is satisfied on reasonable grounds that the exemption is no longer justified or required.
- (9) In determining whether to grant or revoke an exemption the Board is to have regard to the prescribed criteria, if any.
- (10) The Board may publicise exemptions and their revocation in the *Gazette* and in such other ways as the Board thinks fit having regard to the nature of the exemptions.

Appendix 3

3A - Schedule of Proposed Fees to be charged by the TPA

	Fee	Change	\$
1	Application for approval of premises (new and altered) includes inspection	No change - combines previous fees of \$300 (premises registration fee) and \$150 (premises inspection fee)	\$450
2	Annual renewal fee for registration of pharmacy business premises	New fee includes periodic inspection fee	\$400
3	Application for approval of corporate provider (per company or trust)	No change for a single company, Increase of \$100 (11%) for company and trust	\$500
4	Application for approval of new ownership	New fee	\$175
5	Annual return of information from corporate providers	Increase of \$15 (10%)	\$165

3B – Anticipated Operational Budget

Anticipated income derived from fees		\$73 425
Sitting fees and travel expenses	\$12,200	
Costs of inspections	\$6 000	
Administration and overheads	\$50,000	
Total estimated expenditure		\$68 200
Estimated net surplus		\$ 5 225