### **SAMOA**

### **PHARMACY REGULATIONS 2012**

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**PURSUANT** to sections 20 and 28 of the Pharmacy Act 2007, **I, TUI ATUA TUPUA TAMASESE EFI**, Head of State, acting on the advice of Cabinet, **MAKE** the following Regulations:

**DATED** this 22<sup>nd</sup> day of November 2012.

signed: (Tui Atua Tupua Tamasese Efi) **HEAD OF STATE** 

# **REGULATIONS**

## PART I PRELIMINARY

- **1. Short title and commencement**-(1) These Regulations may be cited as the Pharmacy Regulations 2012.
- (2) These Regulations come into effect on the date they are made.
- **2. Interpretation** In these regulations, unless the context otherwise requires:
  - "Act" means the Pharmacy Act 2007;
  - "allied pharmacy professional" means a pharmacy assistant or pharmacy technician registered in accordance with procedures implemented by the Council;
  - "drug" has the meaning in section 2 of the Food and Drugs Act 1967.

# PART II ALLIED PHARMACY PROFESSIONALS

- **3. Qualifications**-(1) The minimum qualification for a pharmacy assistant is:
  - (a) a pass in Secondary School's Pacific Senior School Certificate Biology and Chemistry; and
  - (b) as determined by the Council.

- (2) The minimum qualification for a pharmacy technician is:
  - (a) a Certificate in Pharmacy; or
  - (b) formal pharmacy training as approved by the Council; or
  - (c) work experience in the field of pharmacy for a period of not less than seven (7) years; or
  - (d) as determined by the Council.
- **4. General duties and responsibilities**-(1) It is the responsibility of an allied pharmacy professional:
  - (a) to carry out tasks delegated by a pharmacist and which an allied pharmacy professional is authorised to perform;
  - (b) to refer to a pharmacist any condition or task which is outside his or her competence, education and training;
  - (c) to have a reasonable understanding of the roles of all members of the Pharmaceutical Services of the National Health Service where the allied health professional is an employee of the National Health Service;
  - (d) to have a reasonable understanding of the roles of a pharmacy where the allied pharmacy professional is an employee in that pharmacy.
- (2) In addition to the duties in subregulation (1), an allied pharmacy professional working in a hospital is responsible for:
  - (a) dispensing in-patient medicine as directed by a pharmacist;
  - (b) supplying wards with medicine as directed by a pharmacist; and
  - (c) managing ward stocks and emergency supplies as directed by a pharmacist.
- **5. Duties and responsibilities of a pharmacy assistant**-(1) A pharmacist must supervise the work of a pharmacy assistant.
- (2) The general duties of a pharmacy assistant include the following:
  - (a) to assist a pharmacist in dispensing prescription medicines;

- (b) to assist a pharmacist in arranging drugs in the dispensing area;
- (c) to manage the presentation and storage of medicine;
- (d) to manage stock including ordering, pricing and inventory control;
- (e) to perform house-keeping duties; and
- (f) to perform any other related duties as directed by the supervising pharmacist.

# 6. Duties and responsibilities of a pharmacy technician-

- (1) A pharmacist must supervise the work of a pharmacy technician.
- (2) The general duties of a pharmacy technician include the following:
  - (a) to assist a pharmacist in dispensing prescription medicine:
  - (b) to check that prescriptions meet legal requirements;
  - (c) to enter prescription details in the computer and prepare labels for drug;
  - (d) to maintain computer held patient records, if any;
  - (e) to answer any queries about prescription drug;
  - (f) to assist a pharmacist in the general running of the pharmacy; and
  - (g) to perform any other related duties as directed by the supervising pharmacist.
- (3) In a retail pharmacy, a pharmacy technician may also advise customers on non-prescription medicines, health or grooming related products.
- **7. Professional standards**-(1) Every allied pharmacy professional must comply with the professional standards determined by the Council.
- (2) Any allied pharmacy professional who does not comply with any of the professional standards is subject to disciplinary action.
- **8. Disciplinary procedures**-(1) Disciplinary action may be taken against an allied pharmacy professional for:

- (a) any breach of the professional standards;
- (b) any act or omission by an allied pharmacy professional in the course of that allied pharmacy professional's work which negligently, carelessly, unreasonably, or recklessly places the life or health of any person at risk;
- (c) any criminal offence committed by an allied pharmacy professional which is in any way associated with the work or duties of that allied pharmacy professional; or
- (d) any breach or failure to observe a lawful direction given by a pharmacist or requirement imposed by any person empowered by law or contract to give directions or impose requirements on an allied pharmacy professional which relate to the work or duties of that allied pharmacy professional.
- (2) Disciplinary action taken by the Council against an allied pharmacy professional must be in accordance with the procedures under Part V of the Healthcare Professions Registration and Standards Act 2007.

# PART III DISPENSING DRUGS

- **9. Dispensing of drugs**-(1) No person shall dispense drugs unless he or she is:
  - (a) a pharmacist registered under the Pharmacy Act 2007; or
  - (b) an allied pharmacy professional acting under the supervision of a pharmacist; or
  - (c) an assistant or shopkeeper in a shop or business or place dispensing non-prescription drugs; or
  - (d) a registered nurse or midwife employed in any of the health services, institutions or bodies for which the National Health Service is responsible; or
  - (e) is a qualified veterinary surgeon dispensing a drug used for treating an animal.

- (2) These regulations do not affect any Government pharmacy or any other officer of the Government who dispenses drugs on the authority of the Chief Executive Officer or the National Health Service.
- **10. Prescription only drugs** Drugs labelled as "prescription only drugs" must be dispensed upon receipt of a medical prescription from a medical practitioner registered under the Medical Practitioners Act 2007 or a dental practitioner registered under the Dental Practitioners Act 2007.

# 11. Criteria on dispensed drugs-(1) All dispensed drugs:

- (a) be labelled and dispensed using generic or trade names, or both names, of a drug product may appear on the dispensing label after the generic name; and
- (b) must bear the following -
  - (i) the strength of the active ingredient;
  - (ii) the complete dose regime in written and graphic form or on graphic form only;
    - (iii) the patient's name;
    - (iv) the date of dispensing; and
    - (v) the quantity of drug dispensed.
- (2) Where a specified brand of a prescribed drug is not available, and the prescriber cannot be readily contacted, a pharmacist may substitute an equivalent generic form or an alternative brand of the drug.
  - (3) The pharmacist must:
    - (a) inform the prescriber at the earliest opportunity when such a substitution under sub-regulation (2) is made: and
    - (b) advise the patient of the substitution made at the time the drug is dispensed.

### PART IV FEES - PHARMACISTS

- **12. Fees** The following fees apply to a pharmacist:
  - (a) registration fee \$200;
  - (b) annual practising certificates \$100.

# PART V MISCELLANEOUS

- **13. Service of documents**-(1) A notice or any other document required to be served on a person for the purposes of the Act may be served:
  - (a) by delivering it personally to the person on whom it is to be served;
  - (b) by leaving it, or sending it by post to a registered mail box, or at his or her usual or last known place of residence or business in Samoa or at the address stated by him or her in any application or other document under this Act; or
  - (c) by so delivering or posting it to any agent or attorney of such person.
- (2) If a notice or other document in sub-regulation (1) is required to be served on the owner or occupier of any premises, and such owner or occupier or his or her place of residence or business is unknown, such notice or document may be served by fixing the same on some conspicuous part of the premises.
- **14. Offences** A person who breaches any of these regulations commits an offence and is liable upon conviction to a fine not exceeding 100 penalty units.

Issued under the authority of the Regulations Ordinance 1953.

Date of Commencement: These Regulations come into effect on the date they are made.

These Regulations are administered by the Ministry of Health.

Copies of these Regulations can be purchased from the Office of the Clerk of the Legislative Assembly.

Printed by the Clerk of the Legislative Assembly, by authority of the Legislative Assembly.