FACULTY OF MEDICINE AND HEALTH – SWHB MEDICATION MANAGEMENT PROVISIONS 2021

1 Purpose and application

(1) These provisions provide for best practice management of medications, which is consistent with the requirements of University policy, the *Poisons and Therapeutic Goods Act 1966 (NSW)* and the *Poisons and Therapeutic Goods Regulation 2008*.

(2) This document reflects currently recognised best practice, while recognising that a single set of provisions cannot address every eventuality. It is not intended, and must not be used, to replace the individual exercise of appropriate clinical judgement and skill.

(3) These provisions apply to all staff, students or affiliates who handle medications in the Susan Wakil Health Building.

2 Commencement

These provisions commence on 26 February 2021.

3 Definitions

TGA reportable event	means an unexpected side effect or problem with a medication, that may or may not have been previously documented, of which the Therapeutic Goods Administration requires to be notified. It does not include medication errors. **Note:** See the Therapeutic Goods Administration adverse event website
AHPRA	means the Australian Health Practitioner Regulation Agency, which administers the Australian national registration and accreditation scheme for health practitioners.
authorised person	means a staff member or affiliate to conduct a particular task at the Susan Wakil Health Building consistently with all endorsements, conditions and notations on their AHPRA registration (where applicable).

authorised prescriber	means a registered health practitioner who is permitted to prescribe medications, subject to any practice conditions imposed by their employer the terms of their registration or by legislation or regulation. This includes, in appropriate circumstances: • a medical practitioner registered by the Medical Board of Australia • a dentist practitioner registered by the Dental Board of Australia • a nurse practitioner registered by the Nursing and Midwifery Board of Australia who is authorised under section 17A of the *Poisons and Therapeutic Goods Act 1966 (NSW)* • a midwife practitioner registered by the Nursing and Midwifery Board of Australia who is authorised under section 17A of the *Poisons and Therapeutic Goods Act 1966 (NSW)* • an optometrist registered by the Optometry Board of Australia with endorsement to prescribe or supply a limited range of medications • a podiatrist registered by the Podiatry Board of Australia with endorsement to prescribe or supply a limited range of medications.
Clinical Governance and Quality Committee	means the committee of that name within the Faculty of Medicine and Health established by clause 8 of the *Health Clinics and Clinical Governance Policy 2020*.
high risk medication	means any medication identified and listed by the NSW Clinical Excellence Commission as having a high risk of causing injury or harm. These include: • anti-infective agents • potassium and other electrolytes • insulin • narcotics (opioids) and other sedative agents • chemotherapeutic agents (see *Safe Work NSW – Using prohibited carcinogens*) • heparin and other anti-coagulants

medication	means any: • drug • medicine • pharmaceutical preparation (including a compounded preparation) • therapeutic substance • over-the-counter medicine • complementary or alternative medicine • vaccine • diagnostic agent for patient administration • medicated dressing • fluid for intravenous use
model of care	has the meaning given in the *Health Clinics and Clinical Services Policy 2020*, which at the date of these procedures is: > means the document which prescribes the way in which clinic and clinical services are delivered for a particular clinic or clinical facility involved in the delivery of patient care not for research or clinical trial purposes.
MyLab	means the University's online system for purchasing and managing hazardous materials used in research and education, including chemicals, gases, medications, and radioactive and biological materials.
scheduled medication	means a medication containing a substance listed in the *Poisons Standard 2020* (also referred to as the *Standards for the Uniform Scheduling of Medicines and Poisons)* which is established as the NSW Poisons List by section 8 of the *Poisons and Therapeutic Goods Act 1966 (NSW)*.
Schedule # substance	means a substance, or a medication containing a substance, listed in the relevant numbered schedule to the *Poisons Standard 2020*.

4 Governance framework

(1) Every person using or handling chemicals, including medications, must familiarise themselves with the legislative, regulatory and University requirements which apply to the substances they are using or handling.

(2) The *Poisons and Therapeutic Goods Act 1966 (NSW)* and the *Poisons and Therapeutic Goods Regulation 2008* regulate medicines, drugs and poisons in New South Wales.

(3) The *Poisons Standard 2020*, also referred to as the *Standards for the Uniform Scheduling of Medicines and Poisons (SUSMP),* is a Commonwealth legislative instrument which:

(a) classifies medicines and poisons into schedules, which are incorporated by reference into the *Poisons and Therapeutic Goods Act 1966 (NSW);*

(b) contains model provisions about containers and labels;

(c) lists products and substances recommended to be exempt from the standard; and

(d) makes recommendations for controls on drugs and poisons.

(4) The Therapeutic Goods Administration (TGA) in the Australian Government Department of Health regulates therapeutic goods such as prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

(a) The TGA classifies medicines, including complementary medicines, according to their risk.

(b) Registered medicines are classified as higher risk, and include prescription and over-the-counter medicines.

(c) Listed medicines are classified as lower risk, and may include vitamin and mineral supplements.

(5) NSW Health's *Medication Handling in NSW Public Health Facilities Policy* applies to all health facilities within its jurisdiction, including where these are provided under contract by a non-government organisation. This includes:

(a) hospitals;

(b) institutions;

(c) clinical services;

(d) outpatient clinics

(e) community health centres;

(f) day centres; and

(g) domiciliary services.

(6) The NSW Clinical Excellence Commission, within NSW Health, monitors trends of medicine-related incidents and provides supporting tools and information about safety and quality in managing medications.

(7) University requirements for clinical trials are set out in the *Clinical Trials Policy 2016* and the *Clinical Trials Procedures 2016*.

(a) Support and information about these requirements is available from the Clinical Trials Support Office and the clinical trials website

5 Procuring medications

(1) Subject to subclause 5(2), all medications must be procured using MyLab, with appropriate approval from the relevant Head of School.

(2) Schedule 8 or Schedule 9 substances must not be purchased until the Pharmaceutical Regulatory Unit of NSW Health has issued the relevant person with an appropriate authorisation to use the drug.

Note: See clause 7 for more information about scheduled drugs and the specific requirements applicable to them.

6 Storing medications safely and securely

(1) The individual who authorises the purchase of a medication in MyLab is responsible for its safe and secure storage.

(2) All medications must be stored consistently with legislative and regulatory requirements, and the manufacturer's instructions.

(a) For most medications, this must be a locked area to which access is restricted.

Note: See clause 7 for more information about scheduled drugs and the specific requirements applicable to them.

(3) Medications must be stored in their original containers, as dispensed or supplied.

(4) Medications requiring refrigeration must be stored at a temperature between 2.0 and 8.0 degrees Celsius (2° - 8° C).

(a) The temperature of the medication refrigerator must be monitored and recorded at least daily.

(b) The medication refrigerator must be regularly physically and visually inspected to check that:

(i) it is clean;

(ii) it contains nothing other than medication;

(iii) the medication within it has no contact with any freezer compartment or element; and

(iv) the refrigerator is functioning appropriately.

(5) If the temperature of the medication refrigerator deviates from the required range, all medications within it must be moved to alternate refrigerated storage, within the required temperature range, immediately.

(6) Vaccines must be stored and managed consistently with the NSW Health Policy Directive 2017_014 *Vaccine Storage and Cold Chain Management*.

7 Scheduled substances generally

(1) Staff, students and affiliates working in the Susan Wakil Health Building must comply with the *Poisons Standard 2020*.

Note: Further information is available from the TGA website *Scheduling of Medicines and Poisons*.

(2) A scientifically qualified person in charge of a laboratory in the Susan Wakil Health Building, or a person acting under their direct supervision, is authorised to possess and use in the Susan Wakil Health Building any Schedule 2, 3 or 4 substance required for the conduct of:

(a) medical or scientific research;

(b) medical or scientific instruction; or

(c) quality control analysis.

(3) A scientifically qualified person in charge of a laboratory in the Susan Wakil Health Building which is used for research, instruction or analysis may apply to the NSW Director-General of Health for authorisation to use a Schedule 8 or 9 substance.

(a) Authorisations are issued to specified individuals and are not transferable.

(b) A person authorised to possess Schedule 8 or 9 substances is responsible for:

(i) training and supervising any person working with these substances under their authority; and

(ii) complying with all applicable legislative and regulatory requirements, including those relating to storage and security.

(4) A person authorised to possess scheduled substances is responsible for storing them appropriately. Schedule 8, 9 and restricted Schedule 4 substances, including refrigerable items, must be:

(a) stored in a separate safe which is:

(i) physically attached to the structure of the premises; and

(ii) kept securely locked when not in use;

(b) transported securely; and

(c) recorded in the relevant drugs register when received or removed.

8 Scheduled drugs registers

(1) A person authorised to possess scheduled substances must maintain a drugs register for all Schedule 8, 9 or restricted Schedule 4 substances that they obtain or use.

(2) Drugs registers must be kept manually, in an approved hard copy format with:

(a) pages that cannot be removed or replaced (i.e. a bound book);

(b) consecutively numbered pages; and

(c) a separate page for each substance, each formulation and each strength.

Note: See NSW Health *Where can I order a drug register?* for further information.

(3) Drugs registers must be retained for at least 7 years after the date of:

(a) the last entry; or

(b) the last time a substance recorded there was received, administered or used.

(4) Any person who receives, administers or uses a Schedule 8 or 9 substance or restricted Schedule 4 substance must record this in the relevant drugs register.

(a) The entry must be:

(i) made on the day of the receipt, administration or use;

(ii) written in permanent ink in English;

(iii) legible, complete, detailed and accurate; and

(iv) signed and dated by the person making the entry.

(b) Each entry must record:

(i) the date and time the entry is made;

(ii) the quantity of the substance received, administered or used;

(iii) the name and address of the manufacturer or supplier of the substance;

(iv) the name and address of the person to whom the substance was supplied;

(v) the purpose for which the substance was received, administered or used; and

(vi) the remaining quantity of the substance (i.e. the balance).

9 Inventory control for scheduled substances

(1) The individual responsible for a register must:

(a) verify the opening and closing balances of each substance recorded in it whenever:

(i) a drugs register is completed;

(ii) a new drugs register is commenced; or

(iii) an inventory is completed;

(b) monitor compliance with the applicable requirements using:

(i) the Scheduled Drugs Compliance Checklist and

(ii) the Medication Management Audit Tool make an accurate inventory of scheduled substances in March and September each year (or as specified by the NSW Director-General of Health) and in doing so:

(iii) endorse the relevant drugs register immediately under the last entry for each substance with the quantity actually held and the date of the inventory; and

(iv) sign each entry.

(2) If:

(a) any amount of any scheduled substance is lost or stolen; or

(b) all or part of a drugs register is lost, stolen or destroyed;

the individual responsible for the register must immediately report the matter to the relevant Head of School.

(3) Upon being notified of a loss or theft the Head of School must immediately:

(a) notify the NSW Director-General of Health by completing and submitting a *Notification of Loss or Theft of Accountable Drug* form;

(b) inform University Protective Services, who will liaise with NSW Police; and

(c) record the incident in the University's *Riskware* online risk management system.

(4) The individual authorised to possess a scheduled substance is responsible for arranging for its destruction when it is to be disposed of. That person must:

(a) require the destruction to be carried out under the direct personal supervision of a registered pharmacist or a police officer; and

(b) record the destruction in the relevant drugs register, including:

(i) the date of destruction;

(ii) the name and professional registration number of any person supervising the destruction; and

(iii) the name and signature of the attending pharmacist or police officer.

10 High risk medications

(1) Except as provided by subclause 10(2), high risk medications must not be used in the Susan Wakil Health Building.

(2) The Clinical Governance and Quality Committee may approve a model of care which involves use of high risk medications, as provided in the *Health Clinics and Clinical Services Policy 2020.*

11 Administering medications

(1) All medications must be handled consistently with the manufacturer's instructions, including using gloves where required.

(2) Generally, only oral medications prescribed by an authorised prescriber and used consistently with that prescription will be administered in the Susan Wakil Health Building.

Note: For further guidance see also NSW Health Policy Directive 2013_043 *Medication Handling in NSW Public Health Facilities*

(3) Research participants may self-administer their own medications, which may be observed and recorded by research staff.

(4) Medications may also be administered by, or directly under the supervision of, an AHPRA registered medical, nursing or pharmacy practitioner.

(5) Students must be supervised consistently with the requirements of:

(a) NSW Health Policy Directive PD 2013_043 *Medication Handling in NSW Public Health Facilities*; and

(b) applicable student placement agreements.

(6) AHPRA registered medical, nursing or pharmacy practitioners may administer or supervise the administration of oral or topical medications:

(a) with the informed consent of the participant;

(b) following standard medication administration processes;

(c) as described in the applicable model of care; and

(d) with approval of the Clinical Governance and Quality Committee.

Note: See the *Health Clinics and Clinical Services Policy 2020*.

(7) Injectable medications may only be used:

(a) as described in the applicable model of care; and

(b) with approval of the Clinical Governance and Quality Committee.

Note: See the *Health Clinics and Clinical Services Policy 2020*

(8) A person who administers a medication must record this in the relevant patient's health care record, as required by the *Health Care Records Management Procedures 2020*.

(9) All drugs listed in the *Poisons Standard* must be used only within the limits, and in the manner, specified in that document.

(10) No Schedule 4, 8 or 9 drug may be used without, or outside of:

(a) a model of care approved under the *Health Clinics and Clinical Services Policy*; and

(b) prior approval from the Clinical Governance and Quality Committee.

12 Reporting medication errors

(1) The prescriber, or the person who administered the medication, must report all medication errors or near misses:

(a) to the affected participant;

(b) to the participant's medical practitioner; and

(c) in the University's *RiskWare* online risk management system.

(2) If an error is serious or likely to cause harm the person who administered the medication, or who observed the participant taking the medication, must seek immediate medical attention by:

(a) providing immediate first aid; and

(b) following the clinical medical emergency procedures for the Susan Wakil Health Building.

(3) Practitioners may also be required to notify their indemnity insurance provider.

13 TGA reportable events

(1) A prescriber, or any authorised person, who observes a TGA reportable event must report it to:

(a) the Therapeutic Goods Administration, using the Adverse Event Report form, by telephone or by email;

(b) the affected participant;

(c) the participant's medical practitioner; and

(d) in the University's *RiskWare* online risk management system.

14 Medication recalls

(1) The Therapeutic Goods Administration administers the process by which medications are withdrawn from supply as a result of concerns about quality safety or efficacy.

(2) Within the Susan Wakil Health Building, participation in this process should be co-ordinated through MyLab.

15 Compliance

The Clinical Governance and Support Office will:

(a) arrange for audits of compliance with these procedures to take place in March and September each year; and

(b) report on the outcomes of each audit to the Clinical Governance and Quality Committee.

NOTES

Faculty of Medicine and Health – SWHB Medication Provisions 2021

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Date registered:	12 March 2021
Date commenced:	26 February 2021
Approved by:	PROFESSOR ROBYN WARD, Executive Dean and Pro Vice-Chancellor, Faculty of Medicine and Health
Review date:	26 February 2026
Related documents:	Health Services Act 1997 Poisons and Therapeutic Goods Act 1966 (NSW) Work Health and Safety Act 2011 (NSW) Poisons Standard 2020 (Cth) Poisons and Therapeutic Goods Regulation 2008 (NSW) Clinical Trials Policy 2016 Health Clinics and Clinical Governance Policy 2020. Medication Handling in NSW Public Health Facilities Policy (NSW Health) Consent to Medical and Healthcare Treatment Manual (NSW Health) High-Risk Medicines Management Policy (NSW Health)

THE UNIVERSITY OF SYDNEY

AMENDMENT HISTORY

Provision	Amendment	Commencing