HUMAN MEDICATION MANAGEMENT PROCEDURES 2023

Issued by:	Executive Dean and Pro Vice-Chancellor, Faculty of Medicine and Health
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Last amended:	19 January 2024 (administrative amendments)
	24 April 2024 (administrative amendments)
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1 Purpose and application

(1) These procedures provide for best practice management of medications, 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 procedures 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 procedures apply to all staff, students or affiliates who handle medications used on humans in University owned or operated clinics.

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

(4) These procedures do not apply to the use of cytotoxic or hazardous medications.

Note: Further information on cytotoxic drugs can be found in the Safework NSW document :- Cytotoxic Drugs and related waste- risk management See clause 20.

2 Commencement

These procedures commence on 1 February 2023.

3 Interpretation

(1) Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have in the *Health Clinics and Clinical Services Policy*.

Note: See clause 6 of that policy.

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 who conducts a particular task at the University 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 who is authorised under section 17B of the *Poisons and Therapeutic Goods Act 1966 (NSW)* • a podiatrist registered by the Podiatry Board of Australia with endorsement to prescribe or supply a limited range of medications. who is authorised under section 17C of the *Poisons and Therapeutic Goods Act 1966 (NSW)*
clinic	means, for the purposes of these procedures, a health clinic owned or operated by the University, as defined in the *Health Clinics and Clinical Services Policy.*
Clinical Governance and Quality Committee	means the committee of The University of Sydney that was established by clause 8 of the *Health Clinics and Clinical Services Policy.*
hazardous medication	means any medication with potential to cause harm and may include: • antineoplastic drugs; • non-antineoplastic drugs; and • drugs with reproductive effects. **Note:** A list of these medications can be viewed in the United States' National Institute for Occupational Health Safety *List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*. See clause 20.

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*, which at the date of these procedures is: 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.
prescription forms	means forms used for prescribing medications including: • medical officers' private prescription pads, • hospital pads; and • forms for computer generation of prescriptions; but excluding medication charts used for prescribing and administering medicines for inpatients.
Riskware	means the University's software application for recording and managing incidents and hazards.

secure storage	means storage within a lockable location to which unauthorised users do not have access.
scheduled medication	means a medication containing a substance listed in the *Poisons Standard* (also referred to as the *Standard 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*
TGA reportable event	means an unexpected side effect or problem experienced by a person using or taking 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*

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*, also referred to as the *Standard 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 Policy Directive* 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, including the University;

(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* and the *Clinical Trials Procedures*.

(8) 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

(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 substances 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 substances 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 constantly monitored.

(b) The following must be recorded at least daily for medications generally, and at least twice daily for vaccines, using an appropriate minimum and maximum thermometer or inbuilt device:

(i) current temperature;

(ii) minimum temperature;

(iii) maximum temperature;

(iv) name and role of the person making the record.

(c) 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 there is any temperature deviation (outside 2° - 8° C) any person observing this must immediately:

(a) notify the person in charge of the medications;

(b) find alternate refrigerated storage arrangements in another medication dedicated refrigerator;

(c) quarantine the affected medications and mark them as “Do not use” until advice is received about their stability;

(d) tape the affected refrigerator shut and mark it as “Not in Use”.

(e) direct all staff in the relevant area not to use the affected refrigerator or medications;

(f) download and review the data from any available data logging report; and

(g) consult the person responsible for medications, as identified in the model of care (e.g., pharmacist) for assistance and advice.

(6) The person responsible for the medications must ensure that:

(a) no medications are returned to the affected refrigerator until it is functioning and stabilised within the required temperature range; and

(b) no medications are discarded until advice has been provided by an appropriate expert (e.g., pharmacist).

(7) Vaccines must be stored and managed consistently with the NSW Health Policy Directive 2017_014 *Vaccine Storage and Cold Chain Management* and *National Vaccine Storage Guidelines ‘Strive for 5’*

7 Prescription forms

(1) Authorised prescribers must obtain prescription forms through an approved secure mechanism, as described in the applicable model of care.

Note: Please see *Stationery you can order* for further information.

(2) Each authorised prescriber is responsible for the security of their prescription forms.

(3) All sites with prescription forms must store them securely in a locked location with restricted access when not in use.

(4) If an authorised prescriber brings their private practice or personal PBS prescription forms to a clinic, they should be retained by the authorised prescriber at the conclusion of their clinical activity.

(a) If this is not possible, the authorised prescriber must arrange for their prescription forms to be stored securely until the prescriber's next attendance at the clinic.

(5) Access to prescription forms in use must be restricted to authorised prescribers.

(6) If prescription forms are lost or stolen, the individual responsible for the prescription form must immediately report the matter to the relevant line manager, who will report the loss to NSW Health Pharmaceutical Services, consistently with NSW Health requirements for *Lost, stolen or forged prescriptions*.

(7) Medication audits must include review of the procurement, distribution, and storage mechanisms for prescription forms.

Note: See Schedule 1

8 Scheduled substances generally

(1) Staff, students and affiliates working at the University must comply with the *Poisons Standard*.

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

(2) Any person authorised to possess scheduled substances is responsible for storing them appropriately.

(3) Schedule 8, 9 and restricted Schedule 4D substances, including refrigerable items, must be:

(a) stored in a separate safe or locked refrigerator which is:

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

(ii) kept securely locked when not in use;

(iii) only used to store restricted Schedule 4D, Schedule 8 and 9 substances apart from all other goods;

(b) transported securely; and

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

(4) Where a key is used to access the Schedule 4D, Schedule 8 and 9 medication storage unit, transfer of the custody of the key must be strictly controlled, including being kept separate to all other keys.

(a) The person responsible for medications in the area should hold the Schedule 8 medication storage unit key or keys during their work shift.

(b) The key holder should hand the relevant key to each registered nurse, midwife, pharmacist, or authorised prescriber requesting access to the Schedule 8 medication storage unit as required.

(c) The person receiving the key must immediately return it after use to the person responsible for the medications.

9 Scheduled drug registers

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

(2) Drug 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: A drug register can be purchased in MyLab. Large and small versions are available.

(3) Drug registers must be retained for at least seven 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 drug 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).

(5) The records required by subclause 9(4) must be completed by two staff members on each occasion.

10 Inventory control for scheduled drugs

(1) The individual responsible for the drugs register must:

(a) be clearly identified for each relevant service or area;

(b) verify the opening and closing balances of each drug recorded in the register whenever:

(i) a drug register is completed;

(ii) a new drug register is commenced; or

(iii) an inventory is completed;

(c) monitor compliance with the applicable requirements using the CGQC *Medication Management Audit Tool* to make an accurate inventory in March and September each year (or as specified by the NSW Director-General of Health) and in doing so:

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

(ii) sign each entry.

(2) An inventory must be completed:

(a) in March and September each year; and

(b) immediately upon assuming control over the place where drugs of addiction are kept for a period of more than one month.

(3) The person responsible for inventory management must be one of the witnesses to the drugs register count in March and September inventories.

(4) If:

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

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

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

(5) 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 and the Office of General Counsel, who will liaise with NSW Police; and

(c) record the incident in *Riskware*.

(6) The individual authorised to possess a scheduled substance is responsible for arranging for its destruction when it is no longer required. That person must:

(a) follow the *University's Disposal and destruction process for scheduled drugs*

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

(c) record the destruction in the relevant drug 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.

Note: For further information– please refer to the University's *Scheduled Drugs Management* intranet page.

11 High risk medications

(1) Except as provided by subclause 11(2), high risk medications must not be used on humans at, or on behalf of, the University.

(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.*

12 Vaccinations

(1) Except as provided in subclause 12(2), only authorised healthcare professionals may prescribe or administer vaccines.

(a) In doing so they must also meet their relevant professional standards and practise within their lawful scope of professional practice.

Note: See *Administration of vaccines – scope of practice for healthcare professionals* for more information

(2) Specified student cohorts may be permitted to administer vaccines under the supervision of an authorised health practitioner, in accordance with a model of care approved under the *Health Clinics and Clinical Services Policy*.

(3) Vaccination providers must:

(a) screen people before vaccination;

(b) obtain valid consent;

(c) ensure that the correct equipment and procedures are in place as required by the *Australian Immunisation Handbook*; and

(d) promptly submit vaccination data to *The Australian Immunisation Register* (AIR)

(4) No vaccinations may be administered 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.

13 Inventory management generally

(1) The person responsible for inventory management must be clearly identified in the model of care and have the required training for the role. e.g., pharmacist, registered nurse.

(2) The person responsible for inventory management must be able to demonstrate a clear governance process for increasing or decreasing holdings of medications or scheduled drugs.

(3) The person responsible for inventory management must complete a full stock-check of all medications and scheduled drugs at least once a year.

(a) The inventory must be physically checked and documented.

(b) The form at Schedule 2 is recommended for this purpose.

(c) The inventory in MyLab should be checked to ensure it is correct and reflects the current containers.

14 Administering medications

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

(2) Generally, only oral or topical medications prescribed by an authorised prescriber and used consistently with that prescription will be administered at the University.

Note: For further guidance see also NSW Health Policy Directive 2022_032 *Medication Handling*

(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, dental, nursing or pharmacy practitioner.

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

(a) NSW Health Policy Directive2022_032 *Medication Handling*

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*.

(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.*

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

(9) All medications 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 substance 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.

(11) The *FMH Infection Prevention and Disease Control Procedures* must be followed to minimise or prevent the risk of infection.

15 Reporting medication errors

(1) The prescriber, or the person who administered the medication, must:

(a) report all medication errors or near misses:

(i) to the affected participant;

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

(iii) in *RiskWare;* and

(b) follow the incident management processes set out in the *Health Clinics and Clinical Services Policy*.

(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 applicable University medical emergency procedures.

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

16 TGA reportable events

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 *RiskWare*.

17 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 University, participation in this process should be co-ordinated through MyLab.

18 Medications used in clinical trials

(1) All clinical trials involving a medication, or an investigative product used on a human, must comply with the *Clinical Trials Policy* and the *Clinical Trials Procedures*.

(2) Clinical trial investigational products and medications must meet all requirements specified for the clinical trial for which they have been approved.

Note: Further information and support is available from the *Clinical Trials Support Office.*

19 Disposing of medications

(1) Unwanted medications:

(a) may include expired, contaminated, or damaged medication, or medications no longer required for use; and

(b) must be disposed of safely and consistently with all regulatory and legislative requirements.

(2) Unwanted Schedule 4D and Schedule 8 medications must be:

(a) included in all routine stock checks pending destruction;

(b) secured in an appropriate Schedule 8 medication storage unit; and

(c) clearly distinguished from useable stock of the same medication, e.g. in a sealed, clear container, with the description and quantity written on the container;

(3) Destruction of scheduled medications must be recorded in all relevant drug register, signed and dated by authorised officer and witness.

Note: For further information see: *Disposal of clinical medications*

20 Cytotoxic and hazardous medications

Cytotoxic and hazardous medications may only be used with the specific approval of the Clinical Governance and Quality Committee, and consistently with the conditions of that approval.

21 Compliance

The Clinical Governance and Support Office will:

(a) arrange for audits of compliance with these procedures to take place, as provided in Schedule 1; and

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

22 Rescissions and replacements

This document replaces the *Faculty of Medicine and Health – SWHB Medication Management Provisions 2021* which is rescinded as from the date of commencement of this document:

NOTES

Human Medication Management Procedures 2022

Date adopted:	16 January 2023
Date commenced:	1 February 2023
Date amended:	19 January 2024 (administrative amendments)
	24 April 2024 (administrative amendments)
Document owner:	Director of Clinical Governance
Review date:	1 February 2028
Rescinded documents:	*Faculty of Medicine and Health – SWHB Medication Management Provisions 2021*
Related documents:	Poisons Standard
	Poisons and Therapeutic Goods Act 2008 (NSW)
	Poisons and Therapeutic Goods Regulations (NSW)
	Australian Immunisation Handbook
	Clinical Excellence Commission
	Cytotoxic drugs and related waste – Risk management
	National Vaccine Storage Guidelines
	NSW Health Policy Directive 2022_032 “Medication Handling”
	Clinical Trials Policy

Health Clinics and Clinical Services Policy

Privacy Policy

Recordkeeping Policy

Clinical Trials Procedures

FMH Infection Prevention and Disease Control Procedures

Healthcare Records Management Procedures

Privacy Procedures

AMENDMENT HISTORY

Provision	Amendment	Commencing
3; 4(3); 8(1)	Updated references and external hyperlink to Poisons Standard	19 January 2024
Throughout	Administrative amendments to remove the year in policy references	24 April 2024

SCHEDULE 1

Audit Schedule

Medication Type	Risk	Minimum required audit frequency	Minimum % of audits completed per quarter	Reported to • Clinic Manager / HOS • Local CQQC • CGQC Consider the following -
Schedule S8,9 and S4D	High	Twice per year in March and September https://legislation.nsw.gov.au/view/whole/html/inforce/current/sl-2008-0392#sec.118	100%	Escalate non-compliance and assess risks
High risk Medications	High	Twice per year	100%	Escalate non-compliance and assess risks
All other Medications	Moderate	Annually at a minimum, once compliance to the procedure has been demonstrated.	100%	Escalate non-compliance and assess risks

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SCHEDULE 2

Inventory record

Generic Name	Batch/lot number	Form (powder, vial, liquid)	Concentration:	Expiry date:	Quantity	If S8/9 -authority to possess	Comments