Health
South Eastern Sydney
Local Health District

DRUG AND ALCOHOL SERVICE BUSINESS RULE SESLHDBR/077

Name	Accountable Medication Management in Drug and Alcohol Services		
What it is	This business rule specifies local protocols required to supplement the primary policy document for medication handling in NSW Health facilities: NSW Health Policy Directive – PD2013-043 Medication Handling in NSW Public Health Facilities.		
Risk Rating	Medium	**Review Date**	August 2020
What it is not	This business rule does not replace any NSW Health or South Eastern Sydney Local Health District policy or other document related to medication supply and handling. It must be used in conjunction with them.		
Who it applies to	All SESLHD Drug and Alcohol clinical staff responsible for managing or working in clinical areas that prescribe, dispense and administer all accountable medication (Schedule 8 and Schedule 4D inclusive).		
What to do **(Must be done in conjunction with State Policy Directive)**	**<u>Accountable Medication Handling in Patient Care Areas</u>** **Medication handling in Drug and Alcohol Services complies with the NSW Health Policy Directive *PD2013-043 Medication Handling in NSW Public Health Facilities* in all aspects with the following additions**: **1. Distribution and Storage** Drug and Alcohol Services (DAS) pharmacy dispenses medication, ensuring medication safety standards. It has no pharmacy licence to purchase medication, nor pharmacy approval number for dispensing under the Pharmaceutical Benefits Scheme (PBS). Pharmacy service in DAS is limited to dispensing within the patient care areas, and therefore does not carry any stock. With the exception of opioid substitution medications and clinical trial medications, accountable drugs are sourced by DAS pharmacy through requisition from either Sydney/Sydney Eye Hospital for Langton Centre or St George Hospital Pharmacy Department for St George Drug and Alcohol Clinic and distributed to clinical units as imprest stock. Schedule 8 medications and Schedule 4D medications are receipted and signed into drug registers by two registered nurses or by a pharmacist and an RN. S8 medications are stored in drug safes, while S4D medications are stored in locked cupboards in each clinical unit as per requirements specified in		

PD2013-043 – Section 6 of Medication handling in patient care areas.

No accountable drugs are kept on medication trolleys.

Opioid substitution medications

The Opioid Treatment Programs (OTP) have the authority from the Pharmaceutical Services Unit (PSU) to directly source opioid substitution medications: namely methadone, buprenorphine/naloxone films and tablets, directly from wholesalers. Medication ordering is done by a registered nurse from OTP and when required, medications are transferred to Ambulatory Care through record of requisitions and signed into drug registers in Ambulatory Care by two registered nurses (RNs) as stipulated in PD2013-043 Section 6.13.1 and as per relevant legislative requirements.

Upon receipt of S8 medications from a wholesaler, two RNs must be present to sign receipt of drugs. Controlled drug receipts with original signatures must be sent by mail to the supplier or as per wholesaler's protocol for S8 drugs. Drug orders and invoices are maintained and kept in files in each clinical area by registered nurses.

OTP accountable medications are signed into the drug registers, and stored in drug safes in each clinical unit as per requirements specified in PD2013-043 – Section 6 of Medication handling in patient care areas.

Drug safe keys are to be carried in person by a registered nurse during clinic opening hours and stored in locked cupboards when the clinic is closed. In case of loss, spare keys are held in locked cupboard known to administration staff, with a key register for each key that staff must sign in and out.

Clinical trials S8 medications

Clinical trials S8 medications are kept in safes. Medications requiring specific temperature control are kept in locked refrigerators, attached to premises as per Section 6 of PD2013-043, and monitored as per "Strive for 5" cold chain recommendations. Fridges with large volume stock are linked to a security alarm system for alerting to temperature excursion.

Clinical trial S8 medications are signed in by personnel authorised in the research protocol approved by a Human Research Ethics Committee (HREC). Balances are to be checked daily during clinic opening hours.

2. Accountable drugs recordings

Section 6 of PD2013-043 applies with the following additions:

- Sets of manual drug registers are kept and maintained by registered nurses in each clinical areas for both S8 and S4D drugs.
- Drug registers are checked daily for balances on days the clinic is open.
- OTP dispensed S8 products are kept as electronic register entries in a software program, currently *iDose* , which complies with *The Poisons and Therapeutic Goods Act 1966* (NSW) and the *Poisons and Therapeutic Goods Regulation 2008* (NSW) and as stipulated in

NSW Health Electronic Drug Register for Pharmacy Feb 2015 http://www.health.nsw.gov.au/pharmaceutical/Documents/electronic-drug-reg-phcy.pdf).

- Clinical research drugs are accounted for as per individual research trial protocols.
- Current drug registers are kept in the relevant clinical areas adjacent to drug safes.
- Non-current drug registers are kept for seven years by pharmacists servicing the clinical areas before archiving or destruction. Clinical trial related S8 registers are kept for a minimum of 15 years, or as per relevant trial protocol.
- Record keeping is in line with SESLHD protocol, and reflected in the district-wide audit tool.

3. Patient's own accountable medications

Patient's own accountable medications in DAS can broadly be classified into two categories:

a) Medications prescribed by DAS doctors, dispensed by DAS pharmacists, signed into patient's own medication registers, waiting for patient's collection. Typically this would be a weaning regimen of benzodiazepines, and dispensed takeaway doses of opioid substitution.
b) Medications prescribed and dispensed outside of DAS, but asked to be brought into the services to be discarded for the purpose of preventing overdose and hence ensuring patients' safety. One typical scenario is take away doses from community pharmacies from which the patient has been transferred to our service due to destabilisation.

Category a) medications are handled in the same manner as all accountable drugs in NSW hospital wards; drugs are signed into registers and balance counted every day the clinics are open.

Category b) medications – patients would be informed that those medications will be disposed of upon entry into our service.

4. S8 drug disposal

Section 6.13.1 and 6.15.2 of PD2013-043 in relation to disposal of medications applies with the following additions:

- S8 medication can only be disposed of in the clinical area by a pharmacist in conjunction with a registered nurse delegated for the task. The Senior Pharmacist is acting as the chief pharmacist for DAS for this intention and purpose, and has the responsibility and authority to delegate or designate pharmacists in the service to dispose of unwanted accountable medications while the nursing unit manager of each clinical area has the responsibility and authority to delegate a registered nurse as the required witness.
- Disposal of S8 drugs must be in accordance with NSW Health Policy Directive PD 2005_132 *Waste Management Guidelines for*

Health Care Facilities in the patient care area. Proper handling prior to destruction include rendering medications unidentifiable, unrecoverable and unusable, before putting in a sharps bin or cytotoxic bins on the premises.

- S8 drugs used for clinical research trials are to be destroyed as per the research trial protocol, which depending on the drugs concerned, may involve witnessed destruction by the PSU and incineration offsite as dictated by the Material Safety Data Sheet (MSDS) when required.

5. Reporting of loss or stolen accountable medication

Follow Section 6.16 in PD2013-043 in all aspects.

In SESLHD Drug and Alcohol Services, the Senior Pharmacist acts for all intents and purposes as the Director of Pharmacy, to be notified of all loss, theft or deficits (including liquid overage and underage that exceeds normal allowance by manufacturer) within 24 hours of its discovery.

The person who detects the loss, theft, or deficit of an accountable medication (including liquid overage and underage that exceeds normal allowance by manufacturer) must:

- Immediately report this fact to the Nurse in Charge of the patient care area who should then inform the DAS Senior Pharmacist and Senior Nurse Manager
- Complete and submit all relevant reports as per PD2007_061 *Incident Management Policy* and to NSW Ministry of Health PSU in full consultation with the DAS Senior Pharmacist and Senior Nurse Manager.

6. S4D and S8 medication audits in DAS

In addition to Section 6.13.4 of PD2013-043, nurse- led monthly audits are conducted in each clinical area by two registered nurses, one of whom must be external to the unit.

The audit tool consists of 17 items, including some DAS specific items and has been endorsed by relevant therapeutics governance units in SESLHD.

A PDF version of the audit tool is available for data collection in Appendix 1 or at – M:\Audits\S8 and S4D.

Results are entered for each register by the auditors into the medication audit tool spreadsheet for the corresponding year and month, see M:\Audits\S8 and S4D. This spreadsheet tallies the number of audit criteria that have not been met for each register.

Monthly summary audit results are reported and discussed at local units, eg, OTP, Ambulatory Care, Pharmacy and site-specific managers meetings and the Patient Safety and Quality (PSQ) Committee to identify and action improvements at the clinical unit or facility level. The PSQ also makes recommendations for LHD wide quality improvements to enhance medication handling compliance.

Biennial Audits are also conducted by pharmacists entailing random matching of actual prescriptions with *iDose* entries, and match stock and delivery receipts. The pharmacy-led audit is performed when the National Inpatient Medication Chart (NIMC) audit is conducted.

7.Transaction and Administration of accountable medication
As per Section 6.13.2 of PD2013-043, the witness to Schedule 8 medication transaction can include "any other person authorised by the registered nurse in charge of the patient care area". The witness must be present during the entire procedure as stipulated in Section 6.13.2. The employee authorised to be a witness must have completed training that addresses the necessary competencies to complete the task and as appropriate be re-assessed and re-accredited for the task.

As per Section 7.1 of PD2013-043, a "suitably trained health care employee may be authorised to administer medication (inclusive of accountable medication) to non-inpatients for the purpose of assisting the patient to self-administer the medication". In the context of DAS, administration of medication must be given in the presence of at least one registered nurse, pharmacist or doctor. The employee authorised to administer medication must have completed training that addresses the necessary competencies to complete the task and as appropriate be re-assessed and re-accredited for the task.

For S8 medication administered as part of OTP, confirmation of patient identity, accuracy and appropriateness of administration is also performed with the assistance of dosing cards, and many inherent functions and prompts in dispensing software – *iDose* - which include: iris scan, photo matching, name, address, DOB, prescription checks, dose confirmation, and dispensing histories.

8. Staff orientation and continuous education
All staff authorised to be a witness or to administer S8 and S4D medications must be orientated and trained in all aspects of medication transaction.

Nursing staff working in patient care areas that handle S8 and S4D medications are required to pass a basic medication safety test or show competency for the task. This is done as a once only event on employment initiation during corporate and clinical orientation. Training is to be provided at the nursing unit level at orientation and as required for continuous improvement, re-assessment of competency and re-accreditation.

The Unit Managers are responsible for provision of training in their unit.

The Senior Pharmacist and the Medical Team Manager are responsible for the orientation and continuous training of medical and pharmacy staff working in clinical areas that prescribe, dispense and administer S8 and S4D medications.

9. Prescribing of S8 in DAS

	Prescribing requirements apply as stated in PD2013-043 with the following additional provisions for DAS: • DAS internal S8 prescription forms (yellow form) are used for prescribing opioid substitutions. • The yellow form, being for internal use only, is designed to have low abuse potential and has tacit approval of the Pharmaceutical Services Unit (PSU) for use in more than one strength of the same formulation of buprenorphine/naloxone films or tablets in the same prescription. For example a 20mg dose of Suboxone will entail two 8mg films and two 2mg films in the same prescription. • This approval also allows for the use of printed labels/addressographs for S8 prescriptions in DAS. The yellow prescription form allows doctors to use printed addressographs which must be signed by the prescriber to confirm patient identity. • All prescribers must obtain relevant authority from Pharmaceutical Services Unit, comply with the *Poisons and Therapeutic Goods Regulation 2008* for prescribing S8 treatment to drug dependent people and undertake training on prescribing drugs of dependence.
When to use it	All incidents of accountable drug handling.
How to use it	Must use in conjunction with all relevant policy documents, business rules and protocols.
Why the rule is necessary	To supplement PD2013_043 – *Medication Handling in NSW Public Health Facilities* for use in Drug and Alcohol Settings – as directed by the policy and the SESLHD Policy and Procedure Governance Sub-committee.
Who is responsible	All clinical staff involved in accountable drug handling.
Ministry of Health / SESLHD reference	• Medication Handling in NSW Public Health Facilities • NSW Health Policy Directive PD2007_061 Incidence management • NSW Health Policy Directive PD 2005_132 Waste management Guidelines for Health Care Facilities in the patient care area • *Poisons and Therapeutic Goods Act 1966* (NSW) • *Poisons and Therapeutic Goods Regulation 2008* (NSW)
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Revision and Approval History

Date	Revision Number	Author and Approval
Nov 2016	**0**	Therese Chan and Annie Malcolm
Feb 2016	**1**	Therese Chan and Annie Malcolm Edited following Draft for Comment phase with all DAS staff
Apr 2016	**1**	Approved Professor Nicholas Lintzeris, Director, Drug and Alcohol Service
June 2017	**Draft**	Processed by Executive Services. Sent to DQUM Committee for endorsement.
July 2017	**Draft**	DQUM recommended some minor changes which were accepted by D&A Services. DQUM Committee approved without the need for further review.
August 2017	**0**	Approved by Clinical and Quality Council.

Appendix 1

South Eastern Sydney Drug Alcohol Service

S4 S8 AUDIT TOOL V2.0 4/2/16

Clinical Unit name	
Date of Audit	
Month being reviewed	
Drug book being audited	
Auditor 1 (from the clinical area being audited)	
Auditor 2 (from the clinical area being audited)	

Criteria	Y/N	Comments
1. One drug, one dosage form, one strength per page		
2. Date documented in full in all entries (dd/mm/yyyy)		
3. Time documented in all entries		
4. Patient's name recorded in all applicable entries		
5. Administered dose recorded in all applicable entries		
6. Prescriber name recorded for all individual patient entries		
7. Each entry signed by 2 staff members one of which must be an RN		
8. Balance check performed at least once every 24 hours by 2 staff members one of which must be an RN		
9. All entries are legible		
10. All incoming stock and balance checks signed in red, and all outgoing or administered stock signed in black		
11. Any discarded, expired and destroyed drug have been signed in by an RN and a Pharmacist		
12. Error entries have not been crossed out or written over, but marked with an * and annotated at margin or footer with explanations, signatures and date		
13. New stock entries record the order requisition numbers		
14. All receiving entries are signed by two staff one of whom is an RN/pharmacist		
15. A current signature list is maintained and regularly used to check signature entries in registers		
16. Key always carried by a RN or otherwise kept locked away accessible only to responsible staff members of the clinical unit.		
17. Methadone manual pump calibrated on audit date (by comparing pump volume with an independent measure such as glass cylinder or precision balance, and make correctional adjustments)		