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Patient Matters

CHAPTER 20 - PHARMACEUTICAL MATTERS

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MEDICATION HANDLING (PD2022_032)

PD2022_032 resinded PD2013_043, IB2013_064, IB2017_045, IB2019_041.

POLICY STATEMENT

NSW Health organisations must have appropriate processes in place to ensure the appropriate, safe, efficient and cost-effective use of medications in NSW public health facilities.

SUMMARY OF POLICY REQUIREMENTS

The Chief Executive is responsible for establishing a Drug and Therapeutics Committee for the governance of medication management.

Each Drug and Therapeutics Committee will be responsible for the governance of quality and safe medication procurement, storage, prescribing, supply, administration and recording protocols and procedures at the facilities assigned to the Committee. The Drug and Therapeutics Committee also has oversight of facility procedures for medication safety alerts, recalls, shortages and incident management.

Facility procedures for the procurement, storage, labelling, prescribing, dispensing, supplying, administering and recording of medications must be in accordance with *the Poisons and Therapeutic Goods Act 1966*, *Poisons and Therapeutic Goods Regulation 2008* and applicable NSW policies and guidelines.

Each facility must establish a High-Risk Medicines Program with a High-risk Medicines Register in accordance with NSW Health Policy Directive *High-Risk Medicines Management* (PD2020_045). Facility procedures must be developed for all high-risk medicines specified on this register.

Authorised prescriber requirements under the *Poisons and Therapeutic Goods Regulation 2008* to direct the administration of medication and issue prescriptions for pharmacist dispensing are in section 4 of the Policy procedures. The Regulation restricts the prescribing of specific medications to certain authorised prescribers and/or under the Authority of the NSW Health Secretary. Authorised prescribers may also supply medications for patient take home use from health facility stocks when the Pharmacy Service is not available.

Medications at the Pharmacy Service are under the governance of the director of pharmacy, or authorised pharmacist delegate where there is no director of pharmacy. At a facility where there is no employed/contracted pharmacist the medication supply service is managed by the director of nursing or medical superintendent authorised by the Chief Executive. Schedule 8 medications are to be stored in a safe or vault apart from all other medications and accounted for in a drug register.

Pharmaceuticals prepared for by, or on behalf of, a public health facility, must be managed in accordance with the Policy Directive *Pharmaceuticals – Preparation in NSW Public Health Facility Pharmacy Services* (PD2015_007).

Medications stored and used within a patient care area are under the governance of the registered nurse or midwife in charge. Specific storage requirements apply for Schedule 4 Appendix D and Schedule 8 medications as they are vulnerable to diversion. Schedule 8 medication transactions are to be recorded in a drug register.

Authorised staff administer and supply medications under facility procedures, such as:

- on a medication chart order, or
- on a verbal (face to face), telephone or video call, email or facsimile order, or

- under a Standing Order, or
- under a nurse-initiated medication protocol, or
- under a Schedule 4 medication clinical protocol.

Certain medications require a second person check in specified circumstances.

TheMedication Handling policy in full is available at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2022_032

343(11/08/22)

TENECTEPLASE REPLACEMENT IN PUBLIC HOSPITALS FOR AMBULANCE PARAMEDICS (IB2013_063)

PURPOSE

This Information Bulletin is to provide guidance on tenecteplase replacement in public hospitals for NSW Ambulance Paramedics.

KEY INFORMATION

The Pre-Hospital Thrombolysis (PHT) program is part of the State Cardiac Reperfusion Strategy (SCRS) that is being progressively implemented by the Local Health Districts (LHD) with support from the Agency for Clinical Innovation (ACI) in collaboration with NSW Ambulance.

As part of the PHT program, NSW Ambulance paramedics administer intravenous tenecteplase to eligible patients with ST Elevation Myocardial Infarction (STEMI) prior to the patient arriving at the hospital.

In accordance with an Authority issued under the *Poisons and Therapeutic Goods Regulation 2008* (NSW), a registered nurse in charge (or his/her delegate) of the Emergency Department (ED) of a public hospital that receives a patient following pre-hospital administration of thrombolytic therapy, is permitted to supply a NSW Ambulance paramedic with one vial of tenecteplase 50mg from ED stock, at the time of patient handover (i.e. 1:1 replacement) to restock the Ambulance Medication kit.

A record of the supply of tenecteplase from the ED, signed and dated by the nurse in charge of the ED (or his/her delegate) and the NSW Ambulance paramedic, must be kept for accountability over the movement of prescription medicines and audit purposes.

The replacement vial must be unused and in its original packaging and should have at least six (6) months shelf life prior to the expiry date.

Replacement should occur even if the hospital only holds one vial of tenecteplase 50mg in stock. In such cases, the Local Health District (LHD) and hospitals will determine how the hospital stock will be replaced according to their local pharmaceutical supply policies.

Processes to facilitate the replacement of tenecteplase provided to paramedics by the ED will be established locally.

In most cases, the patient receiving the pre-hospital tenecteplase would have received tenecteplase at that hospital if the PHT program was not in place (or at another hospital within the same LHD).

These replacement arrangements apply only to tenecteplase that has been used for a patient. Expired stock will not be replaced, nor will any other medication used by paramedics.

The procurement, storage, recording, handling and supply of tenecteplase by a hospital must be in accordance with the NSW Ministry of Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities.

196(12/12/13)

APPROVAL PROCESS OF MEDICINES FOR USE IN NSW PUBLIC HOSPITALS
(PD2016_033)

PD2016_033 rescinds PD2008_037

PURPOSE

This policy establishes a standard process for the approval of medicines and their use for listing on hospital formularies, or for individual patient use.

MANDATORY REQUIREMENTS

All public hospitals in NSW must have a formally constituted, multidisciplinary Drug and Therapeutics Committee in place, or have access to a Local Health District or Speciality Health Network Drug and Therapeutics Committee. The Drug and Therapeutics Committee is responsible for governing the medication management system, and ensuring the appropriate, safe, effective and cost-effective use of medicines in the health facility, Local Health District or Speciality Health Network.

All public hospitals in NSW must have a hospital formulary. Prescribers working within public hospitals in NSW may only prescribe medicines included in the relevant hospital formulary and in accordance with this policy.

Each Local Health District or Speciality Health Network must develop and implement local procedures based on the process outlined in this policy.

IMPLEMENTATION

NSW Clinical Excellence Commission is responsible for:

- Monitoring the implementation of this policy.

Chief Executive is responsible for:

- Assigning responsibility, personnel and resources to implement and comply with this policy.

Director of Clinical Governance is responsible for:

- Reporting the status of the policy implementation to the NSW Clinical Excellence Commission by returning the Implementation Checklist (Attachment 4.2) within six months of publication of the policy.

Drug and Therapeutics Committee is responsible for:

- Undertaking approval process of medicines for use in the hospital as outlined in this policy
- Communicating formulary decisions and any related safety requirements to relevant clinicians and medication-related governance committees
- Informing the NSW Therapeutic Advisory Group of formulary and Individual Patient Use (IPU) decisions, as required by this policy.

Clinical Staff who are responsible for submitting formulary applications must:

- Follow the approval process set out by this policy.

1. ABOUT THIS DOCUMENT

This policy establishes a standard process for the approval of medicines for listing on public hospital formularies, or for individual patient use (IPU).
All NSW public hospitals must follow this process for:

- Medicines that are registered or listed on the Australian Register of Therapeutic Goods that have not yet been added to the formulary
- Use of registered or listed medicines in a manner that is not included in, or is disclaimed in, the approved product information for that medicine
- Use of medicines that are not registered or listed on the Australian Register of Therapeutic Goods.

The process set out in this policy, does **not** apply to:

- M edicines supplied through Medicines Access Programs (refer to the Council of Therapeutic Advisory Groups (CATAG) document on *Managing Medicines Access Programs: Guiding Principles for the governance of Medicines Access Programs in Australian hospitals*).
- The approval of medicine use for research purposes. Use of medicines for research purposes must be referred to the relevant Human Research Ethics Committee (refer to NSW Health Guidelines on Human Research Ethics Committees).

1.1 Related documents

NSW Health Policies:

- Conflicts of Interest and Gifts and Benefits
- Drugs – Funding Arrangements for Outpatient Use of High Cost Drugs Not Funded by the Commonwealth
- Medication Handling in Public Health Facilities
- Pharmaceuticals – Preparation in Public Health Facility Pharmacy Services

NSW Health Information Bulletin:

- NSW Hospital Peer Groups 2016

Council of Therapeutic Advisory Groups (CATAG) documents available at www.catag.org.au/:

- Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals
- Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals
- Position statement for the use of complementary and alternative medicines
- Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines.

1.2 Key definitions

Biosimilar	A biosimilar is a subsequent molecular ('follow on') variant of an already registered off-patent biological medicine (the innovator biologic) that: • Has a demonstrable similarity in physicochemical, biological and immunological characteristics, efficacy and safety, based on comprehensive comparability studies • Has been evaluated by the Therapeutic Goods Administration (TGA) according to its guidelines and other relevant European Union guidelines adopted by the TGA. A biosimilar is not a generic version of the innovator biologic and is not considered to be bioequivalent(1).
Drug and Therapeutics Committee (DTC)	The group with delegated responsibility for governance of the medication management system and for ensuring the appropriate, safe, effective and cost-effective use of medicines in the health facility, Local Health District or Speciality Health Network(2). For further information on the role and operation of DTCs, refer to: • CATAG document on *Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals* • NSW Health Policy on *Medication Handling in Public Health Facilities*.
Drug Use Evaluation	A cyclical process where reviews of medication use are followed, where necessary, by strategic interventions with the aim of improving patient care and appropriate use of resources(3).
Hospital Formulary	A hospital specific list of medicines and related information approved by the DTC. It includes, but is not limited to, medicines and medicine-associated products or devices, medication charts, medication use policies, important ancillary drug information, decision-support tools, and facility guidelines(4).
Individual patient use (IPU)	The use of a medicine by an individual patient outside the hospital formulary regulations(4).
Medication	Used singularly throughout this Policy to describe a drug, medicine, pharmaceutical preparation (a medicine presented as a completed formulation following a process of compounding or reconstituting), therapeutic substance, complementary and alternative medicine, vaccine, diagnostic agent for patient administration, medicated dressing and a fluid for intravenous use. The term includes scheduled medication and unscheduled medication.

Off-label medicine use	The use of a medicine other than that specified in the TGA-approved product information including when the medicine is prescribed or administered: • For another indication • At a different dose • Via an alternate route of administration • For a patient of an age or gender outside the registered use[5]. See 1.3 Definitions of categories and conditions for off-label medicine use
Special access scheme (SAS)	Arrangements which provide for the import and / or supply of a non-TGA approved therapeutic good for individual patient use[6].
Unregistered medicine	An unregistered medicine is a medicine or dosage form that is not currently approved for use in Australia and hence is not entered on the Australian Register of Therapeutic Goods[7].

1.3 Definitions of categories and conditions for off-label medicine use[5]

Routine use	Refers to medicines routinely used off-label where: • High quality evidence supports such use • There is a favourable benefit / harm ratio for the intended off-label use.
Exceptional use	Refers to off-label use of medicines where: • There is low or very low quality evidence • The potential benefits may be greater than the potential harms for the specific individual circumstances that meet pre-specified criteria (such as a serious or rare condition and / or no other effective or safe alternative therapy). Approval is patient specific.
Conditional use	Refers to off-label use of medicines where: • The quality of evidence is low to moderate however there is reasonable justification for use in certain types of patients • A DTC-approved protocol or NSW Health Policy / Clinical Guideline guides the therapy • Evidence development is required with systematic reporting of effectiveness and safety outcomes to the DTC and relevant clinicians • There is regular review of continued therapy for an individual and group of patients. Approval applies to a specific group of patients.

See CATAG document, *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines*, for further information on categories and conditions including for Research or Investigational Use.

2. PROCEDURES

All medicines and their use must be approved by the Drug and Therapeutics Committee (DTC) before they can be added to the hospital formulary or for IPU.

All DTCs must have a process in place for regular review of the hospital formulary. The timeframe for review is determined by the DTC.

All public hospitals in NSW must have a hospital formulary. Prescribers working within public hospitals can only prescribe medicines that are listed in the relevant hospital formulary or in accordance with this Policy.

The DTC must have a process in place for non-hospital formulary medicines (such as those prescribed in the community and continued in hospital) with regard to the approval for use, supply during hospitalisation and discharge, monitoring and reporting of use to the DTC.

Members of DTCs and others who may be involved in the approval of applications must disclose any perceived or actual conflicts of interest (see NSW Health Policy on *Conflicts of Interest and Gifts and Benefits*). There must be full disclosure of any significant relationship (financial or otherwise) between the clinician, who request hospital formulary addition or approval of individual patient or patient group use, and the supplier of the product or other significant party.

2.1 Submission processes for hospital formulary and IPU medicines

2.1.1 Submission processes for hospital formulary approval

DTC's approval is required for any hospital formulary listing of a medicine and its use. All medicines, which are under consideration by the DTC for addition to the hospital formulary or variation to an existing hospital formulary listing, must undergo an evaluation process that:

- Critically evaluates the best available patient-based research evidence to support the inclusion on to the formulary. The level of evidence required concerning effectiveness will depend on the specific medicine and the circumstances in which it is proposed to be used. Sufficient evidence regarding the safety spectrum of the medicine will be required to establish an acceptable benefit / harm ratio for the given clinical circumstances (see CATAG document on *Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines*)
- Clearly defines the objectives of formulary addition or update of listed indication(s) with respect to the delivery of patient care including a broad perspective on the scope of the health problem and the expected impact of this change
- Assesses the medicine costs (including costs associated with the use of the medicine such as need for extra resources) and related direct and indirect costs associated with the potential harms and benefits of a new medicine in comparison with existing therapies, including non-pharmacological therapies where appropriate
- Assesses the requirement of a specific medicine protocol in order to standardise and guide judicious, appropriate, effective, safe and cost-effective medicine use
- Assesses the requirement for any specific training, qualifications, skills or competencies to prescribe, dispense or administer the medicine
- If applicable, considers organisational and electronic medication safety requirements.

The DTC must have a standard process to guide decision making when evaluating a medicine for hospital formulary listing. The NSW TAG *DTC decision algorithm for evaluation of medicines* can be used for this purpose.

The DTC must have a standard process for evaluating biological or biosimilar medicines for hospital formulary listing (see CATAG document on *Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals*).

The clinician(s) requesting the hospital formulary addition must complete:

- A hospital formulary submission form for the DTC. The formulary submission should include the objective of formulary addition or indication update
- Where appropriate, a written clinical protocol that includes, as a minimum, indications and circumstances of use, safe prescribing and administration details, contraindications, precautions and interactions with other therapies and common and serious adverse effects.

It is recommended that hospitals use the NSW Therapeutic Advisory Group (TAG) template and tools for hospital formulary submissions: *Formulary submission template*, *Prescribing protocol template* and *Supplementary information template*.

There are additional considerations for hospital formulary submissions for off-label or unregistered medicines (see 2.1.3 Use of off-label or unregistered medicines for requirements).

2.1.2 Application-process for IPU approval

Approval for IPU of specific medicines is required when a therapeutic need exists for a medicine which would not otherwise be available on the hospital formulary[4].

The DTC must have a standard process to guide their decision-making when evaluating a medicine for IPU.

The clinician(s) requesting use of a medicine for IPU should complete:

- The relevant IPU application form for the DTC
- Where appropriate, a written clinical protocol that includes, as a minimum, indications and circumstances of use, safe prescribing and administration details, contraindications, precautions and interactions with other therapy, common and serious adverse effects.

It is recommended that hospitals use the NSW TAG template and tools: *IPU application template* and *Prescribing protocol template* and *Decision Algorithm for evaluation of medicines for IPU approval*.

There are additional considerations for IPU applications for off-label or unregistered medicines (see 2.1.3 Use of off-label or unregistered medicines for requirements).

Multiple IPU requests for the same medication / indication

The DTC must develop and maintain a system to track IPU approvals. High use of a specific IPU medicine should prompt a formulary submission. In these cases, the DTC should advise the applicant when it is appropriate to make a formulary submission and the submission's requirements.

There may be circumstances involving high use IPU medicines where ongoing DTC oversight of use is required, for example, the use of expensive IPU medicines. In these circumstances the clinician and DTC may consider the development of a streamlined IPU approval form for that medicine and its use. Examples of some streamlined IPU approval forms are available on the NSW TAG website.

2.1.3 Use of off-label or unregistered medicines

Prescribers considering use of a specific medicine (hospital formulary or IPU) in an off-label manner, or use of an unregistered medicine, should follow a systematic process (see Attachment 4.1) to assist with their assessment on whether such use is justified and whether they should proceed with an application to the DTC for formulary addition or IPU.

All medicines that are under consideration for off-label or unregistered use must undergo an evaluation process.

The DTC must have policies and protocols for off-label use of medicines and use of unregistered medicines. Policies and protocols must address:

- Consent and documentation requirements as outlined in Table 1, Patient consent and other documentation requirements for off-label and unregistered medicines
- Patient's and / or carer's involvement in any decision-making regarding off-label medicine use
- Medicine information for clinicians, patients and / or their carer
- Monitoring and reporting of outcomes to treatment, including adverse events
- Ongoing supply of medicines following discharge from hospital
- Any TGA requirements for use of the unregistered medicine including patient / carer consent and prescriber and hospital reporting requirements
- Any requirement of specific training, qualifications, skills or competencies.

Where a patient's own medicine is an unregistered medicine, and was commenced prior to hospital admission, prescribing whilst an inpatient must be subject to the IPU approval process.

Off-label medicines

The CATAG Guiding Principles for the quality use of off-label medicines should be used to support decision making by health professionals, consumers and DTCs in their evaluation, approval and use of off-label medicines.

Unregistered medicines

All medicines that are under consideration for unregistered use must undergo an evaluation process that considers, in the first instance, the use of an alternative registered product in accordance with its approval by the TGA. Unregistered medicine use should only be considered when the approved use of a registered medicine does not address the clinical needs of the patient(s).

DTCs should have processes in place that evaluate and manage the risk that may be associated with the use of unregistered medicines, such as those obtained under *Schedule 5A of the Therapeutic Goods Regulation 199*0 (CTH), *Section 19A of the Therapeutic Goods Act 1989* (CTH) and via the Special Access Scheme (SAS).

Conditional registration of a product may occur under *Section 19A of the Therapeutic Goods Act 1989* (CTH), for example, during times of medicine shortage. Use of these replacement products should be evaluated by the DTC to ensure appropriate, safe, effective and cost-effective use.

Table 1: Patient consent and other documentation requirements for off-label and unregistered medicines[5]

Off-label medicine	
Routine use	• Follow usual processes for patient consent to therapy with provision of information and discussion • This should occur as part of routine clinical care and does not require additional measures.
Exceptional use	• Approval is patient specific • Written informed consent should be obtained • Reasons for use should be documented in the medical record • The prescriber should conduct a detailed discussion about uncertainty of benefits and harms with use of the medicine with the patient and / or carer.
Conditional use	• Written informed consent should be obtained • Reasons for use should be documented in the medical record • Approval of use is conditional on further monitoring and assessment of effectiveness and safety • Detailed discussion about these aspects with the patient and / or carer as well as the benefit / harms of available alternatives and potentially sharing information with others is required.
Unregistered (unlicensed) medicine	
• Written informed consent is required • Refer to the TGA website for specific requirements.	

2.2 Management of applications

All applications (hospital formulary and IPU), including urgent out of session applications and the outcome of all applications, must be recorded by the DTC.

The approval of a medicine for hospital formulary inclusion must include the active ingredient, strengths, dosage forms, indications and any restrictions; for example, by prescriber, indication or duration of therapy.

Notification of application outcomes

All applicants (for hospital formulary or IPU) must be informed of the outcome of their application together with details of approved use, including indications of use, any prescribing restrictions and any monitoring and reporting requirements.

The DTC must have a mechanism for reviewing applications and decisions, should an applicant wish to appeal the DTC decision or provide further relevant information.

Processes must be in place for communication of relevant DTC decisions to all relevant clinicians and medication related governance committees.

Urgent applications
In circumstances where use of a specific medicine is required urgently to prevent or minimise harm to a patient, there must be a procedure in place that complies with the formulary application process, to facilitate rapid assessment of the IPU application by a DTC delegate. The circumstances and details of such approvals must be clearly documented and reported for review at the next DTC meeting.

In circumstances of medication shortage or recall of medicines, the DTC must have a process in place to facilitate rapid assessment and approval of an alternative medicine. Formulary application processes must be followed.

2.3 Review of DTC approved medicines
DTC must have a formulary review process in place.

Monitoring and reporting
Processes must be in place for monitoring and reporting outcomes of medicines use to inform systems improvements. Drug Use Evaluation or other clinical quality audit processes should be utilised. Drug Use Evaluation should be included as a standing agenda item for the DTC meeting.

Medication incident reporting and adverse drug reaction reporting
In addition to the usual reporting using the facilities incident management system and the TGA's Australian Adverse Drug Reaction Reporting System, incidents associated with the use of medicines, including suspected adverse drug reactions, must be reported to the DTC for review, evaluation and appropriate action. The evaluation should include the review of any associated clinical protocol for use of the medicine.

2.4 Communication of hospital formulary decisions to other health services

In order to facilitate communication of DTC decisions to the DTCs of other NSW hospitals, Local Health Districts and Speciality Health Networks, the NSW TAG maintains a register of DTC decisions for NSW public hospitals. The register is accessible in the members' section of the NSW TAG website to authorised personnel including DTC members.

The DTCs of the following hospitals (or LHDs that include the following hospitals), should inform NSW TAG of all hospital formulary and IPU decisions, and other DTC decisions as per the template provided to hospitals by NSW TAG:

- Principle referral hospitals (A1)
- Paediatric specialist hospitals (A2)
- Ungrouped acute – tertiary referral hospitals.

(see NSW Health Information Bulletin on *NSW Hospital Peer Groups 2016*).

REFERENCES

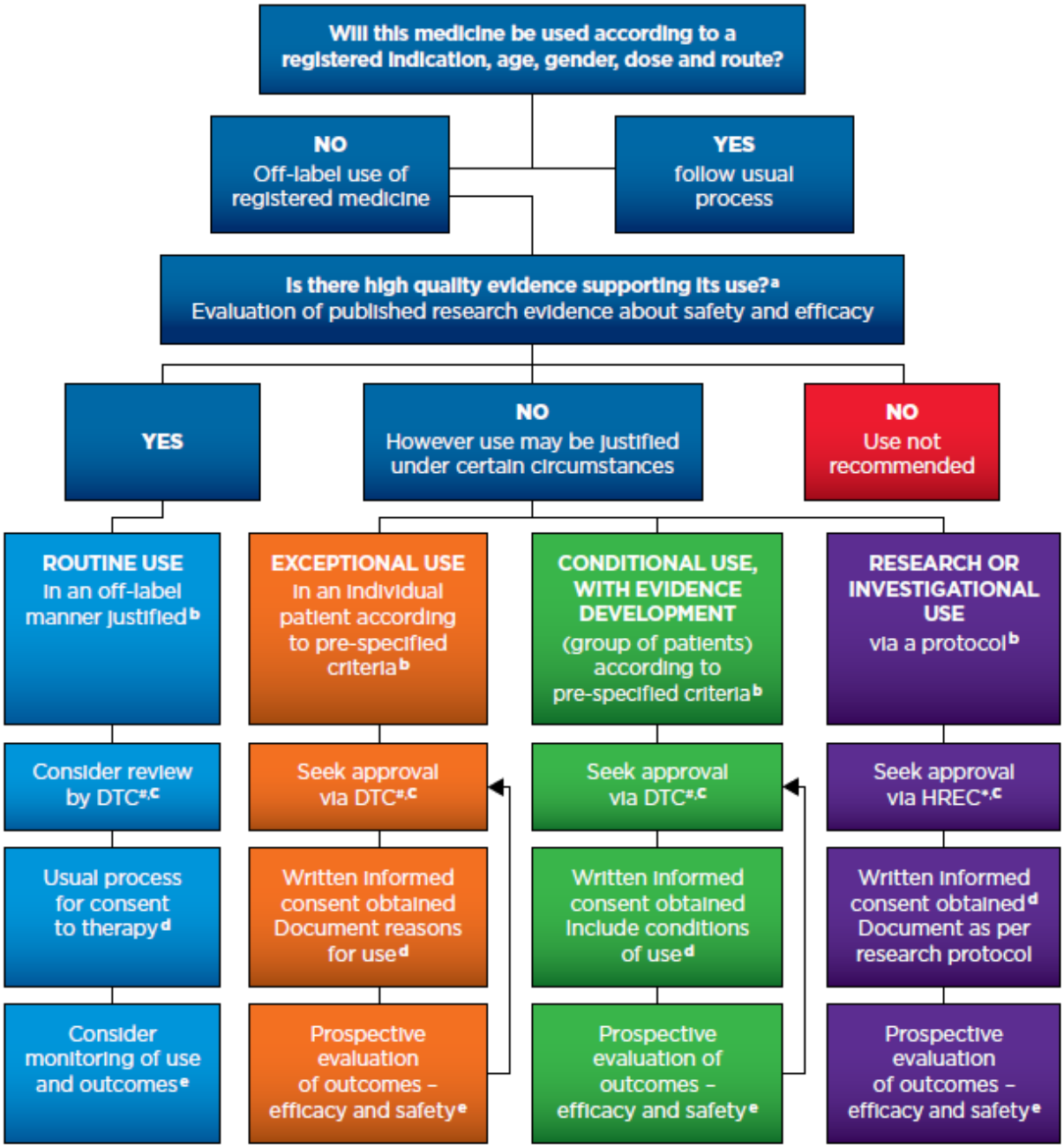
1. Council of Australian Therapeutic Advisory Groups. Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals. Darlinghurst 2015.
2. Australian Commision on Safety and Quality in Healthcare. Safety and quality improvement guide. Standard 4: Medication safety. Sydney 2012.
3. NSW Therapeutic Advisory Group. Drug Usage Evalulation 2013 (accessed 12 November 2015). Available from: www.ciap.health.nsw.gov.au/nswtag/pages/faq-due.html.
4. Council of Australian Therapeutic Advisory Groups. Achieving effective medicines governance: Guiding Principles for the roles and responsibilities of Drug and Therapeutics Committees in Australian public hospitals. Darlinghurst 2013.
5. Council of Australian Therapeutic Advisory Groups. Rethinking medicines decision-making in Australian Hospitals: Guiding Principles for the quality use of off-label medicines. Darlinghurst 2013.
6. Therapeutic Goods Administration. Special access scheme. Australian Government, Department of Health 2015 (accessed 12 November 2015).
7. Gazarian M, Kelly M, McPhee JR, Graudins LV, Ward RL, Campbell TJ. Off-label use of medicines: consensus recommendations for evaluating appropriateness. Medical Journal of Australia. 2006;185:544-8.

4. ATTACHMENTS

1.4 Assessing appropriateness of off-label medicine use[5]

The diagram below is reproduced, with the permission from the Council of Australian Therapeutic Advisory Groups, Darlinghurst, from the document: *Rethinking medicines decision making in Australian Hospitals. Guiding principles for the quality use of off-label medicines.*

Note: This policy does not cover the '**Research or Investigational Use**' pathway.



a See Guiding Principle 2 and Appendix 3 for detailed guidance in answering this question

b See Guiding Principle 2, point 5 for description of criteria for this category

c See Guiding Principle 4

d See Guiding Principle 3

e See Guiding Principle 6

\# Drug and Therapeutics Committee

* Human Research Ethics Committee

4.2 Implementation checklist

Facility:			
Assessed by:		**Date of Assessment:**	
IMPLEMENTATION REQUIREMENTS	**Not commenced**	**Partial compliance**	**Full compliance**
1. The DTC has a standard process in place for evaluating a medicine for formulary listing.	❑	❑	❑
	Notes:		
2. Formulary applications include an application form and a written clinical protocol where appropriate.	❑	❑	❑
	Notes:		
3. The DTC has a standard process for reviewing formulary and IPU applications and decisions where necessary.	❑	❑	❑
	Notes:		
4. There are medication specific policies or protocols available for off-label medicine use and unregistered medicine use.	❑	❑	❑
	Notes:		
5. The DTC has a standard process in place to facilitate rapid assessment of IPU applications.	❑	❑	❑
	Notes:		
6. All applications (formulary and IPU) including urgent out-of-session applications, and the outcome of all applications are recorded by the DTC.	❑	❑	❑
	Notes:		
7. Processes are in place for monitoring and reporting outcomes of medicines use to the DTC.	❑	❑	❑
	Notes:		

PHARMACEUTICALS – PREPARATION IN NSW PUBLIC HEALTH FACILITY PHARMACY SERVICES (PD2015_007)

PD2015_007 rescinds PD2005_200 & PD2005_590.

PURPOSE

This policy consolidates best practice principles for the preparation of pharmaceuticals by, or on behalf of, NSW public health facility Pharmacy Services.

The policy applies to Pharmacy Services at all NSW Public Health Organisations, including where:

a) The provision of the Pharmacy Service to the Public Health Organisation is contracted to a non-government provider, and
b) A contracted provider supplies compounded or reconstituted pharmaceutical preparations to the Public Health Organisation.

MANDATORY REQUIREMENTS

By 1 April 2015 all NSW Public Health Organisations must implement this policy.

IMPLEMENTATION

ROLES AND RESPONSIBILITIES

NSW Ministry of Health:

- Provide the mandatory requirements and standards to support implementation of the policy.

Clinical Excellence Commission:

- Support implementation of the policy where applicable to medication safety.

Chief Executives, Health Service Executives, Managers:

- Assign responsibility, personnel and resources to implement the policy.
- Provide line managers with support to implement the policy in their areas.
- Ensure that local policies, protocols and procedures are in place at each facility to support implementation of the policy.

Drug and Therapeutics Committees:

- Develop, approve and oversee the implementation of local policies, protocols and procedures where required.
- Provide local oversight of the safe implementation of this policy.

Directors of Clinical Governance:

- With other Executive members, ensure successful implementation of the policy within each Public Health Organisation.

1 BACKGROUND

Public health facility Pharmacy Services must not dispense compounded or reconstituted pharmaceutical preparations unless the Director of Pharmacy has confirmed there are appropriate standards of training, skill, facilities, and preparative and quality assurance procedures in place to provide a high level of confidence that the preparations are of a consistently high quality standard.

In accordance with NSW Health Policy Directive Medication Handling in NSW Public Health Facilities pharmaceutical preparations at NSW public hospitals must be formulated in accordance with the Society of Hospital Pharmacists of Australia *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments* (2010) which references the *Guide to good practices for the preparation of medicinal products in healthcare establishments* published by the Pharmaceutical Inspection Co-Operation Scheme under the Pharmaceutical Inspection Convention (PIC/S, 2008) as the standard for medicines prepared in Australian Hospital Pharmacy Departments (Services).

The Society of Hospital Pharmacists of Australia also publishes practice standards relevant to the preparation of pharmaceuticals in various clinical settings which should be implemented where possible (see webpage at http://www.shpa.org.au/Practice-Standards), including for:

- Investigational drugs services.
- Palliative care pharmacy services, and
- Safe handling of cytotoxic drugs.

Additionally, the Pharmacy Board of Australia '*Guidelines for the dispensing of medicines*' (available at http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx) includes guidance on appropriate professional pharmacist practice for extemporaneous dispensing (compounding).

KEY DEFINITIONS

must	Indicates a mandatory action requiring compliance by staff at public health facilities, in accordance with a legislative requirement and/or a NSW Health policy or directive.
should	Indicates a recommended action that should be followed unless there is a sound reason for taking a different course of action.
ingredients of animal or human origin	Any component derived from animals or humans that is contained in, or involved in the manufacture of, the pharmaceutical preparation, including but not limited to: • cell lines, • embryonated chicken eggs, • materials used in cell culture media, • deer velvet antler, • amino acids, and • some excipients such as gelatin.
pharmaceutical preparation	For the purpose of this policy, a medication presented as a completed formulation following a process of compounding or reconstituting, for a purpose that may or may not be an approved indication; a) Compounded pharmaceutical preparation – extemporaneously manufactured using ingredients which may or may not be on the Australian Register of Therapeutic Goods (ARTG). b) Reconstituted pharmaceutical preparation – prepared for administration via a process of mixing pharmaceutical products with other ingredients. This would include pre-filled syringes with one or more ingredients, intravenous fluids with added electrolytes, Total Parenteral Nutrition solutions and parenteral oncology medications.
Pharmacy Service	For the purpose of this policy, a service administered by a Director of Pharmacy responsible for the procurement, distribution, preparation and dispensing of medications as well as the delivery of clinical and other pharmacist practice services.
public health organisation	As defined under the *Health Services Act 1997*, a local health district, statutory health corporation or affiliated health organisation (in respect of its recognised establishments and services).

PRINCIPLES

Approval for the Use of Pharmaceutical Preparations

Public health facility Pharmacy Services should not supply a pharmaceutical preparation not listed or registered on the Australian Register of Therapeutic Goods (ARTG) when a similar or a substantially similar product on the ARTG is available.

NSW Health Policy Directive PD2008_037 Medicine - Evaluation of Medicines for Use in Public Hospitals describes the role of the Drug and Therapeutics Committee in the evaluation and approval of all pharmaceuticals added to a facility's formulary.

Quality Management

To produce a consistently safe and effective product, irrespective of its scale or complexity, for every patient, the Director of Pharmacy of a Pharmacy Service supplying compounding and/or reconstituting pharmaceutical preparations should implement a quality management system which incorporates the elements in the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments* pertaining to:

- Personnel
- Premises and equipment
- Production of preparations
- Documentation
- Quality control
- Contracted services, such as the reconstitution of chemotherapeutic agents
- Complaints and product recalls, and
- Self audits.

PREPARATION, STORAGE, SUPPLY AND HANDLING OF PRODUCTS

Sourcing Completed Pharmaceutical Preparations

Where a preparation is not available as an ARTG registered/listed commercial product and the Director of Pharmacy determines that the Pharmacy Service does not meet the principles in the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments* to formulate the preparation (compound or reconstitute), the preparation must be obtained from either:

a) Another NSW public health facility Pharmacy Service, provided the Director of Pharmacy of the Pharmacy Service obtaining the preparation has confirmed the product was prepared in accordance with the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments*, or

b) A community pharmacy, provided the Director of Pharmacy of the Pharmacy Service obtaining the preparation has confirmed the product was prepared in accordance with the *SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments*, or

c) An Australian manufacturer appropriately licenced under the Commonwealth *Therapeutic Goods Act 1989* to manufacture pharmaceuticals in accordance with the Good Manufacturing Practice for Medicines.

NSW Health Policy Directive PD2014_005 '*Goods and Services Procurement Policy*' and NSW Health '*Goods and Services Procurement Policy Manual*' provides information on purchasing procedures and contracts with providers.

Sourcing Ingredients of Animal or Human Origin

The Director of Pharmacy must implement procedures to ensure that ingredients of animal or human origin are not included in preparations unless the product is on the ARTG. Exception is provided for the use of non-ARTG products where appropriate steps have been taken by the pharmacist, under a protocol approved by the Director of Pharmacy, that the evaluation of the material confirms there is a minimal risk of any disease transmission.

The information from the Therapeutic Goods Administration (TGA) to sponsors of ARTG medications on the use of material of animal or human origin in 'Guidance 10: Adventitious agent safety of medicines' (TGA August 2013) may assist pharmacists in confirming the safe inclusion of such materials in pharmaceutical preparations – see for example reference to the European Pharmacopoeia (Ph. Eur.) Chapter 5.2.8, 'Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products'.

Packing, Labelling, Recording of Pharmaceutical Preparations

Pharmaceutical preparations prepared by or on behalf of the Pharmacy Service must be supplied (when for imprest stock) and dispensed (for a particular patient) in accordance with the packing, labelling and recording requirements in section 5 of NSW Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities, including where the product requires child resistant packaging (in section 5.5.6).

The labelling should also include the name and contact details of the source of a compounded or reconstituted pharmaceutical preparation.

Assignment of Expiry Dates

The Pharmacy Service must assign an appropriate expiry date to compounded or reconstituted preparations and recommend corresponding storage conditions.

Once it has been confirmed that the Pharmacy Service can supply the preparation with a consistently high level of quality assurance, including sterility where appropriate, the limiting factor for assigning the expiry date for use will be the stability of the preparation. The expiry date allocated to a preparation may be varied according to the circumstances, within the limits of the estimated stability.

Accordingly, the Director of Pharmacy of the Pharmacy Service must implement procedures to ensure that:

a) The preparation is chemically and physically stable for the recommended period included on the label, and
b) Appropriate storage facilities are used to maintain the quality of the preparation over that period.

Pre-filled syringes for immediate use

Pharmacists must confirm there is no incompatibility arising from the contact of a compounded or reconstituted pharmaceutical preparation with the materials of the syringe plunger and barrel used to administer the product.

When a preparation in a pre-filled, single-use syringe intended for immediate use is supplied to a patient care area the appropriate staff member must be alerted accordingly.

Storage of Pharmaceutical Preparations

Compounded or reconstituted products should be stored for the shortest possible period prior to administration.

Where not required for immediate use, preparations must be stored in accordance with the requirements in PD2013_043 Medication Handling in NSW Public Health Facilities both at the Pharmacy Service (in section 5) and the patient care area (in section 6).

Temperature storage conditions must be monitored both at the Pharmacy Service and at the patient care area where the preparation is to be used.

For a preparation used to treat a patient in their home, the pharmacist should, where possible, confirm that appropriate storage is available and that the patient is educated accordingly. The use of a temperature monitoring device should also be recommended to the patient.

Discarding and Destruction of Expired, Unusable or Unwanted Pharmaceutical Preparations

Expired, unusable or unwanted preparations must be destroyed in accordance with the requirements PD2013_043 Medication Handling in NSW Public Health Facilities at the Pharmacy Service (section 5.8) and the patient care area (section 6.15).

Where only a part of the prepared unit dose of the product (for example, capsule, ampoule, infusion) is required for administration, the unwanted portion must be discarded in a manner that is safe to the public and renders the preparation unusable. Further information on discarding part units of Schedule 8 preparations is in section 7.9 of PD2013_043 Medication Handling in NSW Public Health Facilities.

MANAGEMENT OF OPIOID DEPENDENT PERSONS ADMITTED TO HOSPITALS IN NEW SOUTH WALES (PD2006_049)

PD2006_049 rescinds PD2005_049. It should be read in conjunction with PD2013_043 'Policy on the Handling of Medication in New South Wales Public Hospitals' and the New South Wales Opioid Treatment Program Guidelines.

This policy directive applies to the management of opioid dependent persons in public or private hospitals.

1 INTRODUCTION

From time to time, opioid dependent persons are admitted to hospitals for the treatment of acute or life threatening medical conditions or injuries or for the management of drug toxicity or withdrawal.

In such cases the prescribing of opioid drugs, including methadone or buprenorphine, may need to be considered. However, without prior proper investigation of the patient's history and physical condition, the immediate prescribing of an opioid drug may be contraindicated.

The policy addresses both the clinical and legal issues of prescribing drugs of dependence for opioid dependent persons and has been prepared to assist medical practitioners in dealing with this situation by outlining the procedures to be followed.

In short, the policy provides for the management of opioid dependent persons:

1. who are on an opioid treatment program and who have been admitted to a hospital for the treatment or assessment of:
   - ⇨ a medical condition and need to continue with their authorised methadone or buprenorphine dose, or
   - ⇨ a painful medical condition and need to continue with their authorised methadone or buprenorphine dose together with such opioid analgesics as are necessary to control pain. In such cases, there should be a clearly identifiable cause of pain or other strong clinical indication requiring analgesia.
2. who are **not** on an opioid treatment program and who have been admitted to a hospital for the treatment or assessment of a medical condition, and require opioid treatment where:
   - ⇨ controlling withdrawal symptoms with opioids is a necessary part of the management of a serious medical condition, and/or
   - ⇨ there is a clearly identifiable cause of pain or other strong clinical indication requiring analgesia.

This policy should be brought to the attention of all hospital staff involved in the management of inpatients who are opioid dependent persons. Additionally, each hospital should ensure that protocols or mechanisms exist for obtaining expert advice on a 24 hour basis on the clinical management of opioid dependent persons.

2 LEGAL RESTRICTIONS ON THE PRESCRIBING OF DRUGS OF ADDICTION TO DRUG DEPENDENT PERSONS

Under the provisions of Section 28 of the *Poisons and Therapeutic Goods Act 1966* the authority of the NSW Department of Health is required to prescribe for or supply to a drug dependent person[1] any drug of addiction (listed in Schedule 8 of the Poisons List[2)].

[1] A '**drug dependent person**' means a person who has acquired, as a result of repeated administration of a drug of addiction or a prohibited drug within the meaning of the *Drug Misuse and Trafficking Act 1985*, an overpowering desire for the continued administration of such a drug.

Therefore, a medical practitioner may not prescribe or supply any drug of addiction (listed in Schedule 8 of the Poisons List) for a person who, in the practitioner's opinion, is a drug dependent person[1] without the prior authority of the NSW Department of Health. The intent of this legislation is to prevent drug dependent persons from "shopping around" to obtain drugs and consequently receiving treatment from more than one medical practitioner concurrently.

In order to facilitate the management of persons admitted to hospitals in New South Wales, an exemption to the above requirement allows a medical practitioner to prescribe a drug of addiction, for up to 14 days, to a person who is an **inpatient** in a **public or private hospital**, without the need to obtain authority from the Department to do so, even when the patient is known or suspected to be a drug dependent person.

3 CLASSIFICATION OF THE OPIOID DEPENDENT PERSON

Opioid dependent persons fall into the following distinct categories:

1. On NSW Opioid Treatment Program (methadone or buprenorphine), *and*
   - 1.1. Not requiring additional opioids for analgesia, *or*
   - 1.2. Requiring opioid analgesia
2. Not on NSW Opioid Treatment Program and
   - 2.1. Requiring opioids to manage withdrawal, *and/or*
   - 2.2. Requiring opioids to manage pain

4 TREATMENT OF AN IN-PATIENT CURRENTLY ON AN OPIOID TREATMENT PROGRAM

These are persons for whom a medical practitioner holds an authority to prescribe methadone or buprenorphine for the treatment of opioid dependence under the NSW Opioid Treatment Program.

After verifying the patient's identity, contact **must** be made with both the authorised prescriber and the opioid treatment dosing point, i.e. the place where the patient attends for dosing, to confirm the current actual dose and the date & time of the last dose, including any take-away doses given. It is important to establish these facts as administration of a dose of an opioid drug may lead to overdose if the patient has received a dose recently or the wrong dose is given.

If there is any difficulty in obtaining details of the authorised prescriber from the patient, Pharmaceutical Services Branch may be contacted during office hours on (02) 9391 9944 for assistance.

(a) Not requiring additional opioids for analgesia

Provided that there is **no medical contraindication** to the administration of an opioid, methadone or buprenorphine should be continued in hospital. It must be prescribed by the patient's hospital medical practitioner in accordance with the dosage regimen prescribed by the patient's authorised methadone or buprenorphine prescriber.

Methadone, in oral liquid form, is administered as a once daily dose. Buprenorphine is a sublingual tablet and may be administered as a daily, second daily or third daily dose. The patient's authorised prescriber should be advised of the approximate length of stay in hospital in order to prevent the patient being exited from the program through 'non-attendance'.

[2] A list of commonly used substances and preparations classified as drugs of addiction (Schedule 8 of the New South Wales Poisons List) - TG 13 is available at http://www.health.nsw.gov.au/pubs/2000/pdf/poisons_gensellers.pdf or from Pharmaceutical Services Branch. Contact the Duty Pharmacist on (02) 9391 9944

When the patient is discharged, the authorised prescriber and the opioid treatment dosing point must be informed in advance of the discharge to ensure that appropriate arrangements are in place for the patient's continuation on the program.

Note: Patients on methadone or buprenorphine are unlikely to exhibit withdrawal symptoms until at least 24 hours after the last dose was administered. In the event that withdrawal symptoms occur and neither the authorised prescriber nor the opioid treatment dosing point can be contacted (e.g., after-hours), the objective signs of withdrawal should be managed, **until such time as contact can be made with the prescriber or opioid treatment dosing point**, as follows:

Methadone - the patient should be administered 30mg methadone orally. If required, further doses of 5mg may be given, titrated against observable signs of withdrawal, up to a maximum daily dose of 40mg.

Buprenorphine - the patient should be administered 4 mg of buprenorphine sublingually with further doses of 2mg, titrated against observable signs of withdrawal. (Note: the maximum dose of buprenorphine on any day should not exceed 32mg.)

(b) Requiring opioid analgesia

Administration of opioid analgesia to persons on a methadone or buprenorphine program must be carried out in consultation with a local Drug and Alcohol specialist. Where contact cannot be made with a Drug and Alcohol specialist, advice on clinical management can be obtained (24 hours a day) from the NSW Drug and Alcohol Specialist Advisory Service, on 9361 8006 (Sydney Metro) or 1800 023 687 (Outside Sydney)

(i) Patient is on a methadone program
Methadone should be administered as in (a) above and additional opioids may be prescribed to relieve pain. If analgesia is not achieved with normal dosage regimens, consultation **must** be undertaken with the patient's authorised methadone prescriber or a local Drug and Alcohol specialist.

(ii) Patient is on a buprenorphine program
Patients maintained on buprenorphine will have a diminished response to opioids prescribed for analgesia, i.e. patients on buprenorphine who suffer severe acute or chronic pain will require higher doses of opioid analgesia than individuals not on buprenorphine treatment. This is because of the 'blocking' effect of the buprenorphine on full opioid agonists.

Generally, if acute or sub-acute analgesia is required, a temporary increase in the buprenorphine dose may provide the additional analgesic cover. Where additional opioid analgesia is required, non-opioid analgesic options should be considered and either used alone or in concert with additional opioid analgesia (e.g. morphine), the dose of which should be titrated according to clinical response.

Patients who develop chronic pain, which does not respond to buprenorphine, may require transfer to methadone. Drug and Alcohol specialist advice on a safe transfer between treatments should be sought if this course is contemplated. The dose of analgesic should be closely monitored if buprenorphine is reduced or stopped. This is because there is the potential for over-sedation, or even overdose, from a high opioid dose as the buprenorphine levels reduce (with a corresponding reduction in the 'blocking' effects of buprenorphine). Where the buprenorphine treatment is stopped completely, the dose of opioid will need to be closely monitored every day for at least 4 - 5 days after the last buprenorphine dose and will probably have to be reduced over time, to avoid an overdose. If in doubt, Drug and Alcohol specialist advice should be sought to ensure safe and effective treatment of pain.

When the patient is discharged, the authorised prescriber and the opioid treatment dosing point must be informed, in advance of the discharge, of the dose and the date of last dose in hospital to ensure that appropriate arrangements are in place for the patient's continuation on the buprenorphine or methadone program.

If there is a need to continue opioid analgesia, the patient's authorised buprenorphine or methadone prescriber should be advised in addition to their general or treating practitioner.

5 TREATMENT OF AN IN-PATIENT DRUG DEPENDENT PERSON NOT CURRENTLY ON AN OPIOID TREATMENT PROGRAM

(a) Where Opioid Analgesia IS NOT Required But Symptoms Of Withdrawal Are Evident. Wherever possible, withdrawal symptoms should be symptomatically treated with non-opioids only.

However, opioids (i.e. methadone in oral liquid form, or buprenorphine sublingual tablets) may be used to treat withdrawal symptoms where:

(i) withdrawal symptoms could reasonably be expected to interfere with the optimum medical management of the patient, or

(ii) the patient is suffering from a serious or life-threatening illness and the patient's premature self-discharge before completion of therapy would prejudice optimum management.

Where methadone is prescribed for the treatment of withdrawal to a person not on an opioid treatment program, 10mg to 20mg per day, in oral liquid form, should be administered in divided doses. The dose may be gradually increased, by 5mg increments titrated against objective signs of withdrawal, to a maximum daily dose of 40mg. The dose may be combined into a single daily dose when stabilized. Doses should not be increased above 40mg daily unless consultation has taken place with a specialist in the management of drug dependence. Patients should be advised that this treatment does not constitute entry to the methadone program. Entry to this program **must** be through approved prescribers.

An alternative strategy is to use buprenorphine sublingually in a dose of 2mg every two to four hours if required to control withdrawal symptoms on day 1. On day 2, the total dose for day 1 should be given as a single dose, and then reduced by 2mg per day thereafter. This is a simpler form of withdrawal management and withdrawal is achieved more rapidly than with methadone. A Drug and Alcohol specialist should be consulted to facilitate this schedule. Patients should be advised that this treatment does not constitute entry to the buprenorphine program. Entry to this program **must** be through approved prescribers.

All patients given methadone or buprenorphine to allay symptoms of withdrawal from opioids should be slowly withdrawn from methadone or buprenorphine prior to discharge from hospital wherever possible. Where it is not possible to complete the withdrawal in hospital or where it is considered appropriate to extend the use of methadone or buprenorphine after discharge, arrangements for continuation should be made following consultation with an approved prescriber. This should be done well in advance of the patient's discharge.

(b) Where Opioid Analgesia IS Required

Tolerance to drugs may necessitate higher doses and/or greater frequency of administration in some cases to achieve satisfactory analgesia compared to an opioid naive patient with a similar condition.

Therefore, for acute problems with a clear diagnosis (e.g. trauma), opioid analgesia, within normal dosage regimens, should be provided in the first instance; above normal dosage or unduly prolonged prescribing should take place only after consultation with a specialist in the management of drug dependence. If contact cannot be made, advice on clinical management can be obtained (24 hours a day) from the NSW Drug and Alcohol Specialist Advisory Service, on 9361 8006 (Sydney Metro) or 1800 023 687 (Outside Sydney).

- **FURTHER INFORMATION**

Advice regarding the nearest approved methadone or buprenorphine prescriber can be obtained from the Pharmaceutical Services Branch of the NSW Department of Health (phone (02) 9391 9944).

General information may be obtained from the Duty Pharmaceutical Adviser, Phone (02) 9391 9944 or at the Branch website - http://www.health.nsw.gov.au/publichealth/pharmaceutical/

ACCESS TO DOSING SERVICES IN PUBLIC HOSPITALS FOR PATIENTS ON OPIOID TREATMENTS (PD2021_011)

PD2021_011 rescinds PD2006_052

POLICY STATEMENT

All NSW Health public hospitals and multipurpose services must ensure availability of supervised administration of opioid agonist treatment for patients on the NSW Opioid Treatment Program, where there are no other dosing services available and accessible.

SUMMARY OF POLICY REQUIREMENTS

All staff in NSW Health care settings are to ensure people on opioid agonist treatment experience person-centred, safe and high-quality intervention and care.

Public hospitals and multipurpose services must:

- Support supervised administration of opioid agonist treatment and develop procedures to communicate with local Alcohol and Other Drug (AOD) services to facilitate case management and support.
- Comply with safe practice and environment standards as per routine hospital accreditation.
- Ensure the appropriate procurement, storage, supplying, dispensing, administration and disposal of opioid agonist medications in line with the *Poisons and Therapeutic Goods Act* (1966); any current relevant regulations; and the NSW Health Policy *Medication Handling in NSW Public Health Facilities* (PD2013_043).
- Factor the requirements of this policy requirement into disaster planning and business continuity management.
- Ensure physical, electronic and procedural safety for patients and staff.
- Provide support and education for staff as appropriate, informed by the Local Health District AOD services.

Public hospitals and multipurpose services are also encouraged to consult with the Local Health District AOD services for clinical and strategic advice in developing and maintaining opioid treatment services. The Drug & Alcohol Specialist Advisory Service (DASAS) is also available for clinical advice.

Local Health District AOD services must:

- Develop procedures to communicate with public hospitals and multipurpose services to facilitate case management and support for patients receiving opioid treatment.

- Provide support and guidance as needed to public hospitals and multipurpose services dosing patients on opioid treatment.

For further information regarding the NSW Opioid Treatment Program, please see the following guidelines:

- *NSW Clinical Guidelines: Treatment of Opioid Dependence* (GL2018_019)
- Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence

INFORMATION SHARING - NSW HEALTH & DoCS - OPIOID TREATMENT - RESPONSIBILITY - CHILDREN UNDER 16 (PD2006_085)

1. PREAMBLE

1.1 In February 2006, Cabinet endorsed the development of a protocol between the NSW Departments of Health and the NSW Department of Community Services (DoCS) to facilitate exchange of information between these agencies where methadone is being made available to DoCS clients.

1.2 This protocol facilitates inter-agency exchange of information to assist DoCS casework staff to assess whether a child or children under 16 years of age is/are at a risk of harm due to a person's misuse of opioids while participating in an opioid treatment program. It complements and has been developed in the context of a number of key policies including the *NSW Drug and Alcohol Services Plan, the NSW Interagency Guidelines for Child Protection Interventions 2006* and the *Interagency Guidelines for the early intervention, response and management of drug and alcohol misuse*.

1.3 Participation in an opioid treatment program is considered a positive treatment option for individuals struggling with ongoing illicit opioid use. The focus of this protocol is information sharing to facilitate determination of whether, in specific cases, misuse of drugs supplied on the treatment program, and/or other circumstances in the household, combine to create inadvertent or deliberate risk of harm to children.

1.4 Accidental ingestion of takeaway doses of methadone by children or deliberate dosing of children by adults can be fatal. Takeaway doses of buprenorphine also present potential risk of harm to children. These risks are not confined to young children. The nature of the risk varies according to the age of the child. While accidental ingestion or deliberate dosing of methadone is a high risk for young children (under the age of six), risk of self-administration and experimentation increase with age and are most likely in adolescence.

1.5 Opioid treatment therapies involving methadone and buprenorphine are a medically accepted way of treating heroin addiction. Over thirty years of clinical experience and research has established that methadone is highly effective at retaining people in treatment, suppressing heroin use and associated crime, and reducing the risk of overdose and HIV. Research also confirms that buprenorphine treatment is effective in achieving these objectives. The most appropriate opioid treatment medication for a client is a clinical decision made by the prescribing practitioner and will reflect a wide range of factors related to the history of the client's drug use and treatment and other medical conditions. The effective treatment of opioid dependence is a long-term issue. Any reduction in dose or withdrawal from treatment must be monitored by the prescriber and conducted gradually.

1.6 Buprenorphine is increasingly used as an alternative to methadone in opioid treatment programs. The pharmacological characteristics of buprenorphine differ from methadone. The different characteristics of buprenorphine allow it to be consumed sublingually (under the tongue) in tablet form. As it can take between 2 and 7 minutes for the drug to be absorbed, it is thought to be unlikely that a child would be able to save the tablet in their mouth for long enough to absorb it. In contrast to methadone there have been no reported deaths of children from an overdose of buprenorphine in Australia and it is considered by the medical community to be a safer drug than methadone. However, there is insufficient evidence to provide assurance that buprenorphine is safe if ingested by children. When a client on buprenorphine is to be given takeaways, a combination formula is used, buprenorphine-naloxone. The combined product is designed to reduce the likelihood of clients injecting or diverting takeaway medication.

1.7 The NSW Department of Health authorises health practitioners to prescribe opioid treatment to persons registered on an opioid treatment program. Prescribers can be either public (career medical officers, registrars, drug and alcohol staff specialists, drug and alcohol nurse practitioners, visiting medical officers) or private (general practitioners, drug and alcohol nurse practitioners, psychiatrists).

1.8 In New South Wales approximately 60% of clients on opioid treatment receive their prescriptions from a private prescriber. The dispensing of the medication is most commonly provided through public or private outpatient clinics, community pharmacies and local hospitals (particularly in rural areas).

1.9 Prescribers are issued with NSW Health clinical guidelines relating to their role in methadone and buprenorphine treatment. The NSW Clinical Guidelines for the Treatment of Opioid Dependence recently revised by the NSW Department of Health include an updated chapter on takeaways that was revised in consultation with DoCS. These Guidelines specify the contraindications to providing methadone and buprenorphine takeaway doses, including current child welfare issues or DoCS involvement of children under 16 in a household.

2. RELEVANT LEGISLATION AND DOCUMENTS

2.1 The client information disclosed to DoCS under this protocol relates to the safety, welfare and wellbeing of a child or children and is provided in accordance with the *Children and Young Persons (Care and Protection) Act 1998.* The *NSW Health Privacy Manual, Version 2* identifies health information disclosed in this manner as exempt from privacy provisions of the *Health Records and Information Privacy Act 2002*.

2.2 The sections of the *Children and Young Persons (Care and Protection) Act 1998* that are relevant to this protocol are outlined below.

- Section 24 of the *Children and Young Persons (Care and Protection) Act1998* provides for a person to report to DoCS where he or she has reasonable grounds to suspect a child is at risk of harm. Reports made under this section in good faith are protected, and cannot generally be used against the reporter in litigation or formal disciplinary action.
- Section 27 of the *Children and Young Persons (Care and Protection) Act 1998* imposes a mandatory obligation on health service providers (including medical practitioners) to notify DoCS if in the course of their work, they form reasonable grounds to suspect a child is at risk of harm.
- Section 248 of the *Children and Young Persons (Care and Protection) Act 1998*. This section allows DoCS to require a "prescribed body" to provide DoCS with information relating to the safety, welfare and wellbeing of a particular child or young person or a class of children or young persons. Public health organisations under the *Health Services Act* (such as area health services) and organisations that provide health services to children are prescribed bodies.

2.3 Health Privacy Principle 11 of the *Health Records and Information Privacy Act 2002* provides personal health information can only be disclosed for the purposes for which it was collected, or other purposes recognised by the Act. These include release with consent, release where there is a serious risk of harm to a person and release authorised by a law (such as the *Children and Young Persons (Care and Protection) Act 1998).*

2.4 Under Section 28A of the *Poisons and Therapeutic Goods Act 1966* practitioners must apply to the Director-General to be approved as a prescriber of methadone and buprenorphine for the purpose of treating opioid dependent individuals in the state of New South Wales. Approvals are subject to several conditions one of the conditions being to follow conditions specified in the *NSW Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Treatment (2006)*.

2.5 Reporting requirements for prescribers employed in Area Health Services are also covered in NSW Health documents, Policy Directive PD2013_007 *Child Wellbeing and Child Protection Policies and Procedures for NSW Health*.

3. OBJECTIVE

3.1 This protocol facilitates the sharing of information between the NSW Department of Health's Pharmaceutical Services Branch (PSB), opioid treatment prescribers and DoCS child protection casework staff concerning persons who are registered to receive opioid treatment (methadone or buprenorphine).

3.2 Information shared under this protocol is intended to assist DoCS to assess the risk of harm to children that arises due to their potential exposure to methadone or buprenorphine that is dispensed to registered opioid treatment clients so that the appropriate child protection responses may be initiated, where necessary.

3.3 The NSW Department of Health and DoCS have key roles in ensuring that DoCS child protection casework staff are adequately informed about the benefits and risks of standard treatments for opioid dependence and are able to obtain accurate information from prescribers to assist with assessment of risk of harm to children where concerns are reported in relation to opioid dependent persons.

4. TARGET CLIENT GROUP

4.1 Children under 16 years of age [as defined in the *Children and Young Person (Care and Protection) Act 1998*] who are at a risk of harm due to their relationship with a person undergoing opioid treatment.

4.2 The two categories of children are covered under this agreement are:

a. Children subject to current DoCS involvement where there is an open case plan; and
b. Children, whether known to DoCS or not, who become known to a prescriber through the prescriber's contact with a client in opioid treatment.

5. GENERAL ROLES AND RESPONSIBILITIES

5.1 The requirements to be discharged by public prescribers in sharing child protection information with DoCS in accordance with this protocol are based on the general obligations on NSW Health staff:

a. To make a report to the DoCS Helpline where he or she has reasonable grounds to suspect a child or young person is at risk of harm in accordance with sections 24 and 27 of the *Children and Young Persons (Care and Protection) Act 1998*, and

b. To provide DoCS with information relating to the safety, welfare or wellbeing of a child or young person when directed to do so by DoCS under section 248 of the *Children and Young Persons (Care and Protection) Act 1998.*

5.2 For private prescribers the obligations on reporting to DoCS are based on:

a. Conditions imposed on their authority to prescribe under the *Poisons and Therapeutic Goods Act 1966* and associated regulations that require prescribers to comply with the *NSW Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Treatment (2006),* including to provide to DoCS casework staff information relevant to possible risk of harm to children as required under this protocol; and/or

b. The general requirement on private prescribers who work in an incorporated practice that provides services wholly or partly to children to comply with sections 27 and 248 of the *Children and Young Persons (Care and Protection) Act 1998*

5.3 NSW Health will review any unreasonable non-compliance by private sector prescribers to the reporting requirements in this protocol. This may result in a prescriber's authorisation to prescribe methadone and buprenorphine being revoked.

5.4 DoCS is responsible for assessing risk of harm to children covered by this protocol.

6. ROLES AND RESPONSIBILITIES RELATED TO CHILDREN SUBJECT TO CURRENT DOCS INVOLVEMENT

6.1 Where DoCS has an open case plan suggesting a parent or carer's misuse of an opioid or opioid treatment, including takeaway methadone or buprenorphine, DoCS will request information from PSB under section 248 of the *Children and Young Persons (Care and Protection) Act 1998* to establish current or recent participation in the opioid treatment program on the basis that in these circumstances the information is relevant to the safety, welfare and wellbeing of the child or young person.

6.2 In accordance with section 248, PSB will provide information to DoCS on whether the subject of the query is registered on the opioid treatment program or was registered for opioid treatment 30 days prior to the date of the request.

6.3 PSB will also provide DoCS with contact details of the current prescriber or most recent prescriber for those who are not on the program but were on the program in the 30 days prior to the request.

6.4 Following receipt of information that the subject of the request *is not* on the program and has not been on the program in the 30 days prior to the request, DoCS casework staff will pursue enquiries about opioid and/or other drugs through relevant section 248 enquiries of Area Health Services.

6.5 Many adult clients will have had treatment provided by the Area Health Services, not only in relation to opioids, but also for treatments relating to other drug or alcohol problems. The PSB database only holds information relating to schedule 8 drugs.

6.6 Following receipt of information that the subject of the request *is* on the program *or has been* on the program in the 30 days prior to the request, DoCS will contact the prescriber to request further information. This information request will focus on establishing whether there may be risk of harm concerns for a child or children as a result of the person's opioid treatment, particularly where takeaway doses are involved. Specifically, DoCS will request the following information:

- The prescriber's knowledge about the client's compliance with treatment;
- Whether the prescriber has sighted or examined a client's child/children in the preceding three months, the reasons for the examination and any associated concerns for the child/children's health and safety;
- Any recent observations that may indicate that the client's parenting is compromised;
- Any current concerns the prescriber has for the health and safety of a child/children based on knowledge of the client, the client's compliance with their treatment regime and/or any other issues that may impact on the safety of the child/children.

6.7 Questions for DoCS casework staff to ask of the prescriber during their initial query are at Attachment A. This is to alert prescribers to the information that will be pertinent to caseworker inquiries about their clients.

6.8 Following contact by DoCS, the prescriber will conduct an assessment of the most recent treatment review and determine whether another review is necessary (as per the *NSW Clinical Guidelines for the Treatment of Opioid Dependence 2006*).

6.9 In reviewing the appropriateness of takeaway doses the prescriber should always include dialogue with the dispenser (in most cases, a pharmacist). The dispenser may occasionally observe children, who attend dosing with the client and may be able to provide additional information as to the stability of the client. The outcome of any review, including dialogue with the dispenser should be documented.

7. ROLES AND RESPONSIBILITIES RELATING TO CHILDREN NOT SUBJECT TO DoCS INVOLVEMENT

7.1 The prescriber will conduct a normal review of the person's treatment regime (as per the *NSW Clinical Guidelines for the Treatment of Opioid Dependence 2006*), including dialogue with the dispenser (in most cases, pharmacist).

7.2 A prescriber who has a reasonable concern (based on their regular review of the person's current social circumstances) that a child/children under 16 years of age is/are at a risk of harm due to an adult's misuse of opioids.

a. Make a report to the DoCS Helpline
b. Identify him or herself as a prescriber, and
c. Provide to DoCS all relevant information that will assist DoCS to make an assessment of the risk of harm for the subject child or children. Provide to the DoCS caseworker all information about the person that may impact on a child's safety, welfare and well-being, based on their knowledge of the client and their compliance or non-compliance with their treatment regime.

7.3 DoCS will review any report received from a prescriber in accordance with existing practices.

7.4 A prescriber contacted by DoCS in response to a report will provide the caseworker with any additional information they have that is relevant in assisting the caseworker to complete an assessment of any child at risk concerns.

8. MONITORING, REPORTING AND EVALUATION

8.1 DoCS and the NSW Department of Health will monitor the operation of the protocol.

8.2 The protocol is to be formally reviewed and evaluated by DoCS in conjunction with the Department of Health no later than two years after the date of commencement. The results of this review will be reported to the respective Directors-General within 3 months of the completion of the review. A particular focus of this review will be the effectiveness of the protocol in responding to the issues identified by the Cabinet decision that authorised its development.

GLOSSARY

Mandatory Reporter

A person who as part of their professional or paid work or as the supervisor/manager of a person who as part of their professional or paid work, delivers health care, welfare, education, children's services, residential services or law enforcement to children or young persons.

Mandatory reporters are required under Chapter 3, Part 2, section 27 of the Act to make a report to DoCS if they suspect that a child is at risk of harm as detailed in Chapter 3, Part 2, section 23 of the Act.

Any prescriber who is not a mandatory reporter within the scope of the Act is required by directive of the Health Minister to report risk of harm under the terms of this protocol.

Mandatory Report

A report made to DoCS, usually via the Helpline to convey a concern about a child or young person who may be at risk of harm. The circumstances of risk of harm are outlined in Chapter 3, Part 2, sections 23, 24, 25 and 27, Chapter 7, Part 2, sections 120, 121 and 122 of the Act.

Risk of harm

Risk of harm is present if there are current concerns that a child or young person may suffer physical, sexual, psychological and/or emotional harm as a result of what is being done or not done by another person, often an adult responsible for their care. Risk of harm is defined in Chapter 3, Part 2, and section 23 of the Act.

Open case plan

A report on a child or young person has been allocated to a DoCS' caseworker for further assessment

PSB Database

An electronic database primarily used to issue authorities to medical practitioners to prescribe drugs of addiction (schedule 8) as required under section 29 of the *Poisons and Therapeutic Goods Act 1966*. This includes authorities to prescribe methadone or buprenorphine under the NSW Opioid Treatment Program, narcotic analgesic for the treatment of chronic pain, stimulants for the treatment of ADHD, etc.

Diversion/diverted dose

The misuse of a prescribed drug, most commonly for selling or injecting

Takeaway dose

A dose of methadone or buprenorphine to be taken in an unsupervised setting, usually at home. Takeaway doses are only provided after careful assessment of the client's stability.

Attachment A
Typical questions for DoCS Caseworkers to Ask Prescribers

Factors that may impact on parenting and/or risk of harm	Prescriber Comment Any risk of harm concerns identified
Is the client prescribed takeaway doses? Which treatment is prescribed - methadone or buprenorphine? How long has the client been on takeaway doses? When was the last review? Did the review consider impacts on any children the person may be caring for? Did the review identify any issues of concern?	
Are there any current issues with the client's compliance with treatment? If yes, please describe these issues. Is the client prescribed any other medication? If so, what?	
In the last 3 months, have you sighted or examined the child or siblings of the child about whom DoCS has a report?	
Are there any observations you have made in the last three months, which may indicate that parenting is compromised, eg. occasions when the child/ren looked ill, neglected, stressed or was/were otherwise behaviourally demanding? How did the client interact with the child/ren? Was the client aware of the child's needs?	
What is the client's behaviour like at prescriber practice/dosing site (i.e. no aggressive/ threatening behaviour towards staff/others reported)	
Has the client indicated whether there are any significant life events impacting upon them at this time (eg. relationship breakdown, pregnancy, grief or loss, legal issues, lack of housing)	
Does the client present with any other mental/ physical health needs?	
Do you have any information about the client's current: Employment/education or training Accommodation status	

RAPID OPIOID DETOXIFICATION - GUIDELINES (GL2011_009)

GL2011_009 rescinds GL2005_027.

PURPOSE

The purpose of *NSW Health Guidelines on Rapid Opioid Detoxification* is to provide information on a procedure which may be conducted in private health facilities, licensed for Rapid Opioid Detoxification (ROD) as per the *Private Health Facilities Regulation 2010* under the *Private Health Facilities Act 2007*. In accord with the regulation, Rapid Opioid Detoxification Class private health facilities must comply with the *Drug and Alcohol Withdrawal Clinical Practice Guidelines - NSW*.

KEY PRINCIPLES

ROD is not currently conducted NSW's public sector nor is it likely to be in the foreseeable future unless in the context of a clinical trial, thus the key principles of these guidelines are to ensure patients undertaking ROD procedures in a private health facility licensed for the purpose of ROD:

1. have been well informed of the treatment they are undertaking including potential risks and alternative treatment options;
2. have been advised verbally and in writing that rapid opioid treatment and naltrexone implants are still experimental treatments;
3. are advised verbally and in writing that naltrexone implants used in Australia have not been approved by the relevant regulatory authorities;
4. can competently provide signed, informed, consent to treatment;
5. have been satisfactorily assessed as appropriate for the treatment; and
6. are adequately monitored and supported during and post treatment.

The guidelines align with the *Private Health Facilities Regulation 2010* under the *Private Health Facilities Act 2007* which provides the recommended standards for the settings in which ROD is undertaken ensuring they are appropriately and adequately equipped. Refer section 4.1.7.

Further, the guidelines provide Public Hospital Emergency Departments and the like with appropriate recommendations on how to best manage patients who present post ROD treatment with complications and/or those who present in medical settings who are in continued treatment with naltrexone (including those with naltrexone implants).

USE OF THE GUIDELINE

As per the *Private Health Facilities Regulation 2010* (amended) under the *Private Health Facilities Act 2007*, compliance with the *NSW Health Guidelines on Rapid Opioid Detoxification* is a condition of a private health facility license for the purpose of ROD.

In addition these guidelines provide recommendations for clinical staff in medical settings such as Public Hospital Emergency Departments and the like for the management of patients who may present post ROD procedures with complications and/or patients presenting who are in continued naltrexone treatment (including naltrexone implants).

The Guidelines can be downloaded at
http://www.health.nsw.gov.au/policies/gl/2011/GL2011_009.html

FUNDING ARRANGEMENTS FOR OUTPATIENT USE OF HIGH COST DRUGS NOT FUNDED BY THE COMMONWEALTH (PD2005_395)

A number of high cost drugs prescribed in NSW for outpatient usage are not funded through the Pharmaceutical Benefits Scheme, Repatriation Pharmaceutical Benefits Scheme, or Section 100 of the *National Health Act* and may be subject to the provisions of this Circular. The responsibility for defining the high cost drugs that are subject to these funding arrangements is delegated by NSW Health to the NSW Therapeutic Advisory Group (NSW TAG), in consultation with Directors of Pharmacy and Drug Committees of tertiary units.

The NSW TAG defines High Cost Drugs for the purposes of these arrangements as medicines which:

1. are not listed for subsidy on the Schedule of Pharmaceutical Benefits under either Section 85 or Section 100 of the *National Health Act*, and
2. incur acquisition costs equivalent to or more than $500 per week per drug per patient (subject to annual review by NSW TAG), and
3. require particular expertise for management of patient care.

And which:

4. are being used in accordance with the Approved Product Information, **or**
5. are being used in a manner that is supported by high quality clinical evidence

Therapy with high cost drugs not funded by the Commonwealth should only be initiated in tertiary units (principal or major referral hospitals) with the approval of the hospital Drug Committee. Where the patient being treated at the tertiary unit resides in another Area, the initiating Area Health Service should inform the Area Health Service (or the appropriate hospital Drug Committee with delegated authority) in which the patient resides. This enables queries or clarifications regarding the clinical indications for the drug to be discussed and resolved between the Areas prior to the transfer of costs.

The Area Health Service of the unit initiating therapy is responsible for financing the cost of the drugs for twelve months from the date of discharge from the episode during which the therapy was commenced, or for twelve months from the date of commencement if therapy was initiated on a non-inpatient basis. After twelve months the responsibility for financing passes to the Area of residence of the patient. Notification and billing should occur at an Area level between CEOs.

To avoid duplication of supplies, the Area initiating treatment should give the Area of residence details of the therapy including the patient's initials, address, date of birth, date of commencement, quantity and cost of the drug at least three months prior to the transfer of funding responsibility. Notification of intention to bill should be made by way of a standard notification form developed by NSW TAG (available on the NSW TAG web site: http://www.nswtag.org.au).

These arrangements should not be used to cover:

1. Drugs that are being used in the context of a formal research protocol;
2. Drugs that are being used in "exceptional" circumstances (as described in *NSW Health Department IB2004/15: Off-Label Use of Medicines and Use of Medicines Obtained under the Commonwealth Personal Importation Scheme in NSW Public Hospitals)*;
3. Drugs that are being used under the Special Access Scheme.

In such circumstances, the patient should continue to attend the hospital where the research or exceptional use was approved, unless new approvals are obtained via the local hospital and/or service provider. Financing of such therapy remains the responsibility of the hospital that has facilitated approval for such use.

For the purpose of this circular, outreach clinics are considered part of their original tertiary unit. However, the responsibility for supply and funding of drug therapy prescribed as a result of outreach clinic consultations is the responsibility of the Area Health Service in which the outreach clinic is located, unless such drug therapy has been specifically identified under the outreach service agreement.

These arrangements do not apply to financing outpatient chemotherapy cycles.
NSW TAG may be contacted at **nswtag@stvincents.com.au**.

83(11/03/10)

NSW CLINICAL GUIDELINES: TREATMENT OF OPIOID DEPENDENCE

(GL2018_019 and abbreviated version GL2018_018)
GL2018_019 rescinds GL2006_019

The Guidelines provide clinical guidance and policy direction for opioid agonist treatment in NSW. They align with national directions and recommendations, and incorporate the latest international clinical evidence.

This Guideline can be downloaded at
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2018_019

An abbreviated version of the Guideline is availabed at
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2018_018

308(30/07/18)

ACCREDITATION OF COMMUNITY PRESCRIBERS – S100 HIGHLY SPECIALISED DRUGS FOR HIV AND HEPATITIS B (PD2019_005)

PD2019_005 rescinds PD2013_055

PURPOSE

The purpose of this Policy Directive is to detail the NSW Health requirements for the accreditation and authorisation of non-affiliated medical practitioners or nurse practitioners to prescribe Highly Specialised Drugs (HSD) under section 100 (s100) of the Commonwealth *National Health Act 1953* for the treatment of Hepatitis B (HBV) and Human Immunodeficiency Virus (HIV). S100 HSD are medicines for the treatment of conditions, which, because of their clinical use or other features, may generally only be prescribed by specialist medical practitioners affiliated with public or private hospitals with appropriate specialist facilities. As it is important that people living with HBV and HIV have access to high quality health care in primary care settings, the s100 HSD Program also provides for non-affiliated medical practitioners and nurse practitioners to be accredited to prescribe s100 HSD used in the treatment of HBV and HIV. With the introduction of new direct acting antiviral (DAA) treatments for Hepatitis C, it is now out of scope for inclusion as an s100 Highly Specialised Drug requiring accreditation and authorisation of community prescribers. In March 2016 the new DAAs for Hepatitis C were listed on the Pharmaceutical Benefits Scheme. The DAAs are now available on both the General Schedule (S85) and under the HSD Program (S100). Medical practitioners or nurse practitioners experienced in treating Hepatitis C, or in consultation with a specialist experienced in treating Hepatitis C, can now prescribe DAAs under General Schedule (S85) and prescriptions can be dispensed through community pharmacies.

308(31/01/19)

MANDATORY REQUIREMENTS

A non-affiliated medical practitioner or nurse practitioner may only prescribe HSDs for HBV and HIV if they are authorised as a community prescriber as outlined in this policy.

IMPLEMENTATION

1. The Ministry of Health will appoint approved clinical authorities who will:

   1.1 Convene a Clinical Advisory Committee/s with sufficient specialist experience and knowledge to adjudicate applications for community prescribing accreditation in the areas of HBV and/or HIV.

   1.2 Recommend to the Ministry of Health applicants the Clinical Advisory Committee/s have assessed as having suitable grounding and experience for community prescribing with reference to any relevant clinical standards, treatment guidelines, models of care and government directives.

   1.3 Periodically adjudicate community prescribers' ongoing suitability for community prescribing accreditation, with reference to recent clinical practice, continuing professional development (CPD), and links with appropriate specialists and specialist treatment facilities.

   1.4 Annually, or on request, provide the Ministry of Health with a copy of the register of community prescribers who continue to be suitable for community prescribing accreditation in accordance with item 1.3. The register shall include at least the following fields: Title, First Name, Last Name, Practice Address, Post Code, Phone, Email, Provider Type, Affiliated Specialist and Specialist Treatment Facility.

   1.5 Maintain a register of accredited community prescribers.

2 The Ministry of Health is required to:

   2.1 Provide a mechanism for community prescriber and training programs that reflect relevant clinical standards, treatment guidelines, models of care and government directives.

   2.2 On the basis of recommendations made by an approved clinical authority (per items 1.2 and 1.4 above), authorise community prescribers to prescribe HSD.

   2.3 Notify community prescriber applicants of the outcome of their applications.

   2.4 Oversight execution of a declaration that outlines the terms of the community prescriber program.

   2.5 Annually issue a list of authorised HBV and HIV community prescribers to NSW public hospital pharmacy departments.

3 Local Health Districts are required to:

   3.1 Ensure that all HSD prescribing, dispensing and claiming is done in line with Commonwealth and State requirements for the HSD Program, including establishing appropriate audit processes.

1. BACKGROUND

1.1 About this document

Highly Specialised Drugs (HSD) are medicines Highly Specialised Drugs (HSD) are medicines for the treatment of conditions, which, because of their clinical use or other features, may generally only be prescribed by specialist medical practitioners affiliated with public or private hospitals with appropriate specialist facilities. As it is important that people living with HBV and HIV have access to high quality health care in primary care settings, the HSD Program also provides for non-specialist medical practitioners and nurse practitioners to be accredited to prescribe s100 HSDs used in the treatment of HBV and or HIV for dispensing at a public hospital pharmacy department.

1.2 Key definitions

Affiliated medical practitioner: refers to a staff hospital specialist or visiting or consulting specialist of a hospital with HBV or HIV facilities.

Approved clinical authority: refers to a committee or organisation recognised by the Ministry of Health under this policy as having sufficient medical expertise to assess community prescribing accreditation applications.

Community prescriber: refers to a medical practitioner or nurse practitioner accredited and authorised to prescribe HSDs in accordance with this policy.

1.3 Legal and legislative framework

The HSD Program is a joint initiative of the Australian Government and the states and territory governments. The Program operates under section 100 of the *National Health Act 1953* (Cth). Section 100 allows for special arrangements to be made for the supply of drugs that, because of their clinical use or other special features, are restricted to supply through public and private hospitals that have appropriate specialist facilities.

A medical practitioner or nurse practitioner, who is not affiliated with an appropriate specialist unit at a public or private hospital, may only prescribe HSDs with the approval of the state or territory.

Patients must be under appropriate medical care. They must also be an eligible person under the *Health Insurance Act 1973* (Cth). An eligible person must be:

- an Australian resident;
- a person covered by a Reciprocal Health Care Agreement, or
- an eligible overseas representative.

2. PRESCRIBING

2.1 HSD Prescribing for HBV or HIV Medications

To write HSD prescriptions, a prescriber must be a medical practitioner issued with a PBS prescriber number and meet at least one of the following:

2.1.1. A visiting or consulting hospital medical specialist practitioner affiliated with a recognised specialist treatment facility.

2.1.2. An accredited community prescriber authorised by the Ministry of Health to prescribe HBV medication as outlined in Section 2.2 of this policy.

2.1.3. An accredited community prescriber authorised by the Ministry of Health to prescribe oral HIV medication as outlined in Section 2.3 of this policy.

2.1.4. A hospital medical practitioner or community general practitioner in exceptional situations where it is impractical to obtain a prescription for HBV or HIV medication from the treating specialist and where that specialist medical practitioner has provided written agreement for the prescription to be issued.

2.2 HBV Community Prescribing (Shared Care)

Authorisation to prescribe maintenance drug treatment for HBV may be granted on an individual basis by the Ministry of Health to non-affiliated medical practitioners or nurse practitioners where the approved clinical authority is satisfied:

2.2.1 The applicant has:
- a) completed appropriate training and assessment requirements;
- b) demonstrated equivalent prior experience;
- c) current authorisation as a HBV community prescriber by another Australian State or Territory participating in the HSD Program.

2.2.2 The applicant demonstrates preparedness to participate in relevant continuing professional development (CPD).

2.2.3 There is evidence of an agreement to participate in shared care with a treating specialist associated with a recognised hospital viral hepatitis treatment facility The applicant and his/her patients have full and timely access to the services of a nominated public hospital viral hepatitis treatment facility.

2.3 HIV Community Prescribing

Authorisation to prescribe oral agents for the treatment of HIV other than by specialists may be granted on an individual basis by the Ministry of Health to non-affiliated medical practitioners or nurse practitioners where the approved clinical authority is satisfied:

2.3.1 The applicant has:
- a) completed appropriate training and assessment requirements OR
- b) demonstrated equivalent prior experience OR
- c) current authorisation as a HIV community prescriber by another Australian State or Territory participating in the HSD Program.

2.3.2 The applicant demonstrates preparedness to participate in relevant CPD.

2.3.3 The applicant can demonstrate an established link with a specialist in HIV, located within a recognised specialist HIV treatment facility approved by the Ministry of Health.

FURTHER INFORMATION

Further information on training courses, eligibility criteria and application procedures are available from approved clinical authorities. At the time of publication, the approved clinical authority for HBV and HIV community prescribing is:

Australasian Society for HIV, Viral Hepatitis amd Sexual Health
Locked Mail Bag 5057
DARLINGHURST NSW 1300
Telephone: (02) 8204 0700
Facsimile: (02) 9212 2382
ashm.org.au

Further information about the HSD Program is available from Medicare Australia at:
medicareaustralia.gov.au/provider/pbs/highly-specialised-drugs/

HIGHLY SPECIALISED DRUGS PROGRAM - GUIDELINES FOR UNDERTAKING CLINICAL TRIALS (PD2005_078)

The purpose of this circular is to advise hospitals of guidelines recommended by the Highly Specialised Drugs Working Party in determining economical appropriateness of clinical trials on their premises.

The Highly Specialised Drugs Working Party (HSDWP) is a committee of Commonwealth, State and Territory officials established under the Australian Health Ministers' Advisory Council (AHMAC) to advise on funding aspects of certain highly specialised drugs.

The HSDWP has recently been discussing ways to assist in ensuring the cost effectiveness of major new drugs supplied through public hospitals. The HSDWP appreciates that clinical trials often carried out in public teaching hospitals have short term cost implications for the hospitals and, in the longer term, can influence the use and cost of the drugs after marketing approval.

The PBS system provides a mechanism for negotiating reasonable costs for PBS listed drugs. There is, however, no such mechanism for public hospitals involved in clinical trials to influence the eventual purchase price of innovative drugs that are prescribed by clinicians but are not listed on the PBS.

In view of this, AHMAC has requested that the HSDWP advise State/Territory Health Departments of Working Party recommendations aimed at allowing the purchaser control over the conditions of supply. The HSDWP has developed guidelines covering economic matters for use by public hospitals in considering whether it is appropriate for a clinical trial to be conducted on its premises. Such considerations should commence **at the earliest possible stage** when sponsors approach specialists to make applications to the hospitals institutional ethics committees to conduct drug trials.

The guidelines recommended by the HSDWP are:

1. Sponsors of products intended for clinical trials should be required to provide a firm indication of the product price following eventual marketing approval. Presently, many sponsors refuse to specify, *at the trial stage*, the subsequent purchase price or price range for the drug. Sponsors should provide hospitals with information on the potential financial implications of maintaining patients on their products if the clinical trial demonstrates acceptable safety and efficacy and marketing approval is obtained.

2. Sponsors should be expected, when appropriate, to design clinical trials to include gathering of data on the value for money of the drug for the use under investigation.

3. Sponsors should undertake to meet all the reasonable direct and indirect costs to hospitals in conducting clinical trials. Over recent years there has been a tendency for sponsors not to meet all the legitimate costs of conducting drug trials. At times, companies provide only the drug without any other financial assistance for the trial.

4. Sponsors should undertake not to introduce any "administration fees" in the period following a drug trial and leading up to registration for marketing, or be prepared to justify any fee.

   Some manufacturers do not, or are slow, in seeking marketing approval and have introduced "administration fees" for the supply of drugs under the Special Access Scheme (SAS) following the conclusion of clinical trials. These are solely determined by the manufacturer and in many cases are equivalent to the intended product price after marketing approval.

It should be noted that the Therapeutic Goods Administration is considering placing a limit on the volume of a product's use under the Special Access Scheme to prevent the Scheme being used as an alternative to marketing.

5. Sponsors should undertake to pay hospitals for preparing individual case reports for products provided through the Special Access Scheme. Some suppliers require ongoing patient profiles during treatment.

6. Unregistered products used in clinical trials cannot be promoted by the sponsor. Hospital staff should be made aware of the code of conduct of the Australian Pharmaceutical Sponsors Association. By this code, the Industry self-regulates promotion of pharmaceutical products. Any infringement of the code should be reported to:

Secretary
Code of Conduct Subcommittee
Australian Pharmaceutical Manufacturers Association
Level 2, 77 Berry Street
NORTH SYDNEY NSW 2060

PRIORITY ACCESS TO PUBLIC OPIOID TREATMENT PROGRAM SERVICES FOR PATIENTS RELEASED FROM CUSTODY (PD2021_027)

PD2021_027 rescinded PD2005_313

POLICY STATEMENT

Patient released from custody in NSW who are on opioid agonist treatment are to be given priority access to public Opioid Treatment Program (OTP) services in local health district in which they reside post-release.

SUMMARY OF POLICY REQUIREMENTS

NSW Health OTP services are to retain patients in treatment, where possible, as they transition between custody and the community. Priority access is to occur regardless of whether the patient has commenced opioid agonist treatment (OAT) in a correctional setting or in the community, or whether the patient has been released from a public or private correctional centre.

Transfer of care arrangements

The custodial health service is to refer the released patient to the local health district for ongoing management. Services must continue the patient's OAT unless clinically contraindicated. The patient can transfer to a private OTP service post-release pending clinical risk assessment and review by the District-based Alcohol and other Drug Service. For Aboriginal patients, this can include linkages to the patient's nearest Aboriginal Community Controlled Health Service.

The custodial health service is to arrange the transfer of care by providing advance notice of the patient's expected release from custody (where possible) and facilitate the booking of initial appointments for the patient to the District OTP service within 24 hours of expected release if the patient is on oral or sublingual OAT. This includes providing relevant documentation to the District.

Where a patient is unexpectedly released from custody and the transfer of care has not been prearranged, the custodial health service is to advise the patient to attend their previous, or nearest, public OTP service and is to provide the patient with relevant contact details.

District services receiving a patient unexpectedly released from custody without a prearranged transfer of care are to contact Justice Health and Forensic Mental Health Network Drug and Alcohol Central Office or the Remote On-Call After Hours Medical Service (ROAMS) and ensure that the appropriate arrangements are made for the patient.

Business Hours (Monday to Friday)

Phone: (02) 9700 2101
Fax: (02) 9700 3605
Email: JHFMHN-DischargePlanning@health.nsw.gov.au

Weekends and Public Holidays

ROAMS
1300 076 267 (Option 3)

District-based services are to have procedures in place to ensure their OTP clinic's authorised practitioner takes over care of the patient (including obtaining a s.29 authority for that patient) as soon as possible.

When patients on OAT transfer from custody to any community-based treatment, the following documentation is to be provided as part of clinical handover of care to the receiving service:

- Details of the custodial health service provider that was managing the patient prior to transfer of care.
- Details of OTP service provider the patient is being referred to for ongoing care.
- The patient's intended address and contact details, if known, when transferring to the community
- An OAT prescription /medication order from the custodial prescriber for the transition period
- Recent administration information including dosing history. If the patient is being treated with depot buprenorphine, then drug administration and dosing history for the last 3 months is to be included.
- A copy of the Patient Identification form including photo
- Recent Clinical Review report detailing the patient's current health concerns and current medications.

Transfer of care considerations for patients on depot buprenorphine

Patients on depot buprenorphine are to be provided with the option of continuing depot buprenorphine, where possible. Where depot buprenorphine cannot be continued in the community upon the patient's release, they may be transferred to sublingual buprenorphine. All transfers to and from depot buprenorphine are to be guided by the NSW Health Clinical Guidelines for use of Depot Buprenorphine.

For patients on **monthly** depot buprenorphine injections, a prescription or medication order for at least one single monthly depot buprenorphine dose post-release must be provided to the new service provider. For these patients, the custodial health service provider will aim for the last dose to be within one to two weeks of anticipated release. This may require flexible administration of the last injection of depot buprenorphine within the three to five-week period from previous dose/s.

For patients on **weekly** depot buprenorphine, prior to release, a prescription/medication order for one single weekly depot buprenorphine injection must be provided to the new service provider, with two repeats.

Transfer of s.29 authorities to prescribe methadone or buprenorphinei

The custodial health provider will ensure patients initiated or continue OAT while in custody will have s29 authority completed in custody. It is the responsibility of the District to ensure the transfer of the authority to prescribe Opioid Agonist Treatment for patient's post-release. The District prescriber is to apply for a s.29 authority to prescribe within 21 days after the patient's release from custody.

Relevant forms are accessed at https://www.health.nsw.gov.au/aod/Pages/depotbuprenorphine.aspx

HIGH-RISK MEDICINES MANAGEMENT (PD2020_045)

PD2020_045 rescinds PD2019_058

POLICY STATEMENT

All NSW Health organisations must have systems in place for the safe management and use of high-risk medicines.

This Policy Directive includes individual policy standards for the following high-risk medicines: hydromorphone, methotrexate (oral), neuromuscular blocking agents, opioids, paracetamol, potassium (intravenous), vincristine and anticoagulants.

SUMMARY OF POLICY REQUIREMENTS

All public health facilities must maintain a high-risk medicines program in accordance with NSW Health Policy on Medication Handling in NSW Public Health Facilities.

All public health facilities must maintain as part of the high-risk medicines program, a specific high-risk medicines register. The specific high-risk medicine register must include medicines used locally within the facility identified to be at 'high-risk' of misadventure.

Local protocols must be developed for all identified high-risk medicines specified on the register. The protocols are to be developed in consultation with relevant specialists and overseen and approved by the District or Health Service Drug and Therapeutics Committee(s) (however named). Protocols must include a timeframe for review.

Each high-risk medicine protocol must include patient monitoring which is relevant and appropriate for the patient's clinical circumstances. This is to ensure a timely response to adverse events or side effects associated with drug treatment.

All public health facilities are to employ strategies to mitigate the risk of medicines on the mandatory local high-risk medicines registers.

Adverse incidents involving high-risk medicines must be reported in the facility incident management system and reviewed through local quality management systems.

The High-Risk Medicines Management: Procedures can be download from:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2020_045

IMPLEMENTATION OF BARCODE SCANNING IN NSW PUBLIC HOSPITAL PHARMACY DEPARTMENTS (IB2014_048)

PURPOSE

To provide information to NSW public hospital pharmacy departments on the implementation of barcode verification in the dispensing process.

KEY INFORMATION

Product selection errors made during the dispensing process can cause adverse drug events leading to patient harm, prolonged hospitalisation and wasted resources.

The implementation of barcode scanning (verification) during dispensing is a patient safety initiative that is known to reduce the rate of product selection errors.

The implementation of barcode verification is supported by the following professional pharmacy bodies and is required under the National Safety and Quality Health Service Standards (Criterion 4.5.2):

- The Pharmacy Board of Australia recommends the use of barcode scanning by pharmacists in all settings and is revising the *Guidelines for dispensing of medicines* to strengthen their position on the use of barcode scanning;
- The Pharmaceutical Society of Australia (PSA) endorses the use of barcode scanning to verify the selection of correct medicines in its *Professional Practice Standard 5: Dispensing*;
- The Society of Hospital Pharmacists of Australia (SHPA) encourages the use of barcode scanners even where legislation does not mandate the practice.

Recommendations

It is strongly recommended that all public hospital pharmacy departments implement barcode verification in dispensing processes.

The following actions will be essential for successful implementation and require advanced planning:

- Directors of pharmacy departments (and/or their delegates) oversee the redesign of the dispensary workflow to incorporate barcode scanning into the dispensing process.
- Barcode verification is incorporated into the dispensary workflow such that it acts as a checking process, rather than a product selection process.
- The requirement to use barcode verification is incorporated into pharmacy department protocols and procedure manuals.
- All pharmacy staff members are made aware of the need to use barcode scanning during dispensing, and undergo appropriate training to do so (see Staff Education).
- Barcode scanning is used just prior to attaching the label to the medicine.
- Regular and routine monitoring of the rate of barcode scanning in the dispensing process. Where scanning rates are low, underlying reasons should be analysed and appropriate remedial action/s are undertaken.

The only **exclusion** to these recommendations is the dispensing of medication packs that do not include an appropriate barcode. This may be because they are:

- Supplied as a part of a trial or study.
- Obtained under the Special Access Scheme (SAS).
- Extemporaneously prepared (i.e. those that are outsourced from external manufacturers, and those prepared locally).

Staff Education

All pharmacy staff involved in the dispensing process including pharmacists, pharmacy technicians and pharmacy interns, should be provided with education and training on how to use barcode scanning to verify product selection during the dispensing process.

The implementation of barcode scanning in public hospital pharmacy departments is expected to be incorporated in the next iteration of NSW Health Policy Directive PD2013_043 '*Medication Handling in NSW Public Health Facilities*'.

Resources

The Clinical Excellence Commission is developing an education package and promotional material to assist pharmacy departments in implementation of barcode scanning. These will be found at http://www.cec.health.nsw.gov.au/programs/medication-safety/barcode-scanning/

The following professional standards can also be accessed online:

- PSA Professional Practice Standards version 4 - 2010: Standard 5: Dispensing https://www.psa.org.au/supporting-practice/professional-practice-standards/version-4
- SHPA Practice Standards: Standards of Practice Guidelines for Hospital Pharmacy Outpatient Services – 2006 [Read-only PDF] http://www.shpa.org.au/Practice-Standards
- Pharmacy Board of Australia: Codes and Guidelines – Pharmacy Guidelines for Dispensing of Medicines http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx

CHANGES TO PRESCRIBING AND DISPENSING OF BOTULINUM TOXIN AND GROWTH HORMONE (IB2015_049)

PURPOSE

From 1 September 2015, new arrangements will be in place to govern the supply of Pharmaceutical Benefit Scheme subsidised growth hormone and botulinum toxin.

This information bulletin provides further detail on the practical implications of the new arrangements for NSW public hospitals.

KEY INFORMATION

GROWTH HORMONE

PBS Changes to prescribing and dispensing

- From 1 September 2015, the way PBS subsidised growth hormone (somatropin) is prescribed, dispensed and accessed is being amended by the Commonwealth to better align with other PBS arrangements.
- Currently, prescribers make a written application to the Commonwealth Department of Health to prescribe growth hormone.
- From 1 September 2015, prescribers will make a written application to the Commonwealth Department of Human Services – Medicare under the PBS Written Authority system.
- Prescriber eligibility criteria will remain unchanged (i.e. the eligible medical practitioner must hold a specialist qualification for the condition).
- Medicare will notify the prescriber of the outcome and the prescriber will be responsible for notifying the patient's parent/carer of the outcome of the application.
- Approved PBS authority prescriptions will be used by the patient's parents/carers to obtain growth hormone supplies at the pharmacy of their choice – the Commonwealth Department of Health will no longer manage the ordering and monitoring of growth hormone supplies.
- Patients will be able to present authorised prescriptions to any PBS-approved pharmacy.

Important practical arrangements and implications for NSW Public Hospitals

- NSW Health is not a signatory to the Pharmaceutical Reforms and therefore under the new arrangements NSW public hospital pharmacy departments are not able to claim the Commonwealth reimbursement for an authorised PBS prescription for growth hormone.
- In NSW this means, when providing a service to a privately referred non-admitted patient, an authorised PBS prescription is provided to the patient/carer who then presents the script to a community or private hospital pharmacy where the supplies will be ordered, delivered and dispensed to the parent/carer.

Co-payments

- Normal PBS patient co-payments will now apply.

For further information, please view the following FAQ link developed by the Commonwealth: http://www.pbs.gov.au/info/general/changes-to-certain-s100-programs

KEY INFORMATION

BOTULINUM TOXIN

PBS Changes for prescribers and hospital pharmacies

- Section 100 Botulinum Toxin Program is being modified by the Commonwealth to align with other PBS arrangements, using PBS prescriptions and s94 Hospital Pharmacy coordination points.
- All changes to the Botulinum Toxin Program will take effect from 1 September 2015.
- Prescribers will no longer need to register with the Commonwealth, but specialists will be restricted, by specialty, to prescribing for specific indications. Details are in the *Criteria for Availability* in the PBS Schedule.
- Only s94 (PBS-eligible) hospital pharmacies will be able to claim reimbursement.
- Community pharmacies are not included in this program.
- Botulinum toxin, and related products, will continue to be listed in the PBS Schedule under *s100 Botulinum Toxin*.

Important practical arrangements and implications for NSW Public Hospitals

- NSW Health is not a signatory to the Pharmaceutical Reforms and as such NSW public pharmacies will not be able to claim PBS reimbursement for botulinum toxin from 1 September 2015.
- In NSW, when providing a service to a privately referred non-admitted patient, prescribers will have two options. The prescribers may either come to an arrangement directly with a s94 pharmacy or with a third party with appropriate arrangements in place, to dispense, deliver and claim reimbursement of the PBS botulinum toxin.
- The private hospital will claim reimbursement online via PBS Online.
- Importantly, the prescriber must arrange with the s94 pharmacy or alternative supplier the appropriate transportation and provision of the toxin so that the patient has no involvement in the transportation.
- Under no circumstances are patients to be in possession or involved in the transport of the botulinum toxin.

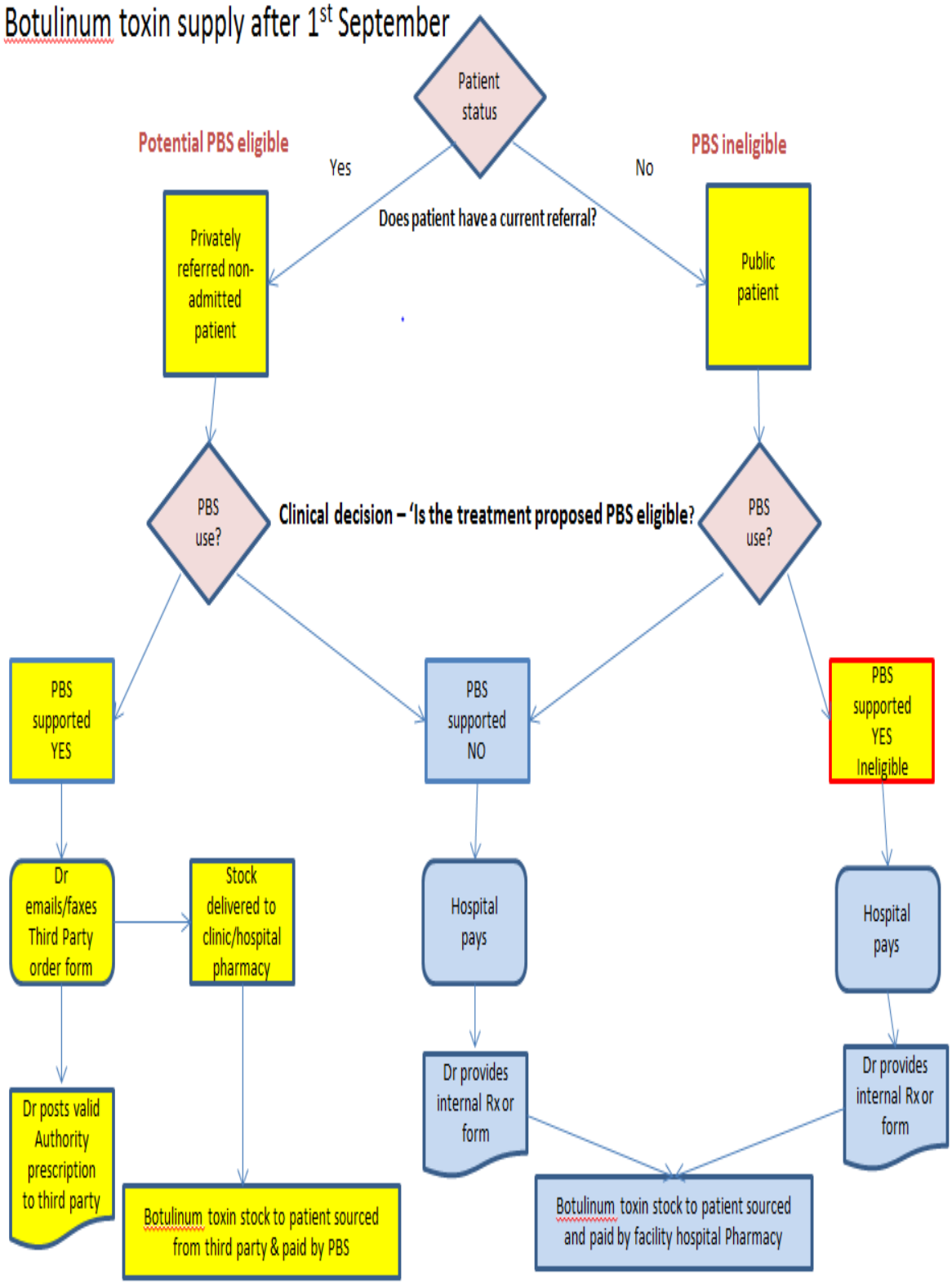
Co-payments

- Normal PBS patient co-payments will now apply to botulinum toxin dispensed at a s94 pharmacy.

An indicative botulinum toxin supply diagram follows.

For further information, please view the following FAQ link developed by the Commonwealth:

http://www.pbs.gov.au/general/changes-to-certain-s100-programs/faqs-botulinum-toxin-25-june-2015.pdf


Botulinum toxin supply after 1st September
Patient status
Potential PBS eligible
Yes
No
PBS ineligible
Does patient have a current referral?
Privately referred non-admitted patient
Public patient
PBS use?
Clinical decision – 'Is the treatment proposed PBS eligible?
PBS use?
PBS supported YES
PBS supported NO
PBS supported YES Ineligible
Dr emails/faxes Third Party order form
Stock delivered to clinic/hospital pharmacy
Hospital pays
Hospital pays
Dr provides internal Rx or form
Dr provides internal Rx or form
Dr posts valid Authority prescription to third party
Botulinum toxin stock to patient sourced from third party & paid by PBS
Botulinum toxin stock to patient sourced and paid by facility hospital Pharmacy

VACCINE STORAGE AND COLD CHAIN MANAGEMENT POLICY STATEMENT (PD2020_028)

PD2020_028 rescinds PD2017_014

POLICY STATEMENT

All NSW facilities must adhere to mandatory vaccine storage and cold chain management requirements to ensure vaccine are stored in accordance with best practice guidelines, vaccine cold chain breaches are identified and managed consistently and efficiently, and all patients receive potent and effective vaccines.

SUMMARY OF POLICY REQUIREMENTS

All facilities must ensure that policies, procedures and protocols are in place for effective vaccine storage and cold chain management according to the current editions of the *National Vaccine Storage Guidelines 'Strive for 5'* and the digital *Australian Immunisation Handbook.*

All vaccines must be stored in a purpose-built vaccine refrigerator that is continually data logged. The data logging report is downloaded and reviewed at least weekly.

All refrigerators must have an audible alarm preferably with a back-to-base alarm or automated temperature monitoring system.

A base-line vaccine storage self-audit is conducted initially and annually in March thereafter (available on the Quality Audit Reporting System – QARS).

Local procedures must be in place to respond to cold chain breaches and power failures, including reporting temperatures outside +2°C to+8°C range to the local public health unit (PHU) on 1300 066 055 within the same working day. Vaccines must be quarantined until advice is received from the PHU.

Cold chain breaches resulting in vaccine wastage or recall and revaccination of patients must be reported in the Incident Management System to facilitate investigation, resolution and minimise the risk of future incidents.

All vaccine refrigerator current/minimum/maximum temperatures are visualised and manually recorded twice daily on the NSW Health vaccine refrigerator monitoring chart.

Staff education should be facilitated through the MyHealth 'Vaccine Storage and Cold Chain Management' module and cold chain management resources available on the NSW Health cold chain webpage.

The Vaccine Storage and Cold Chain Management Policy and Procedures can be downloaded from: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=pd2020_028

TAKE HOME NALOXONE (PD2020_027)

PD2020_027 rescinds PD2019_036

POLICY STATEMENT

NSW Health enables health workers to supply take home naloxone as part of a structured overdose response intervention for the purpose of preventing opioid overdose-related mortality and morbidity, where the conditions and processes described in this Policy are adhered to. It also outlines workforce training and credentialing, governance and medication handling (including ordering, storing and supplying) requirements for participating organisations.

This Policy is relevant to the supply of naloxone to clients for later use and **does not** apply to health workers directly administering naloxone and other emergency procedures in response to a suspected patient overdose in a health service setting.

SUMMARY OF POLICY REQUIREMENTS

This Policy Directive is for the management of clients by health workers of the MSIC, NSW Local Health Districts, Justice Health & Forensic Mental Health Network and the St Vincent's Health Network services who work with clients at risk of opioid overdose.

Eligible health workers at participating services must have successfully completed the Take Home Naloxone training and credentialing requirements set out in the Take Home Naloxone Procedures in order to supply naloxone using this model.

Trained and credentialed health workers who are not otherwise authorised to supply naloxone medications must comply with the Procedures when supplying naloxone.

Medical practitioners and nurse practitioners may follow these Procedures or may continue to follow existing models for prescribing and supply of scheduled medicines.

If pharmacists employed by Local Health Districts are to supply naloxone without prescription, they must do so in compliance with this Policy and within scope of the legislative authority.

The Policy provides the basis for Local Health District Drug and Therapeutics Committees to adopt the THN intervention. The MSIC must adopt and comply with the Policy.

All facilities offering this intervention must implement appropriate governance structures and identify and minimise the risks of adverse events. In facilities that adopt the intervention a designated Responsible Person (a senior nurse, pharmacist, medical practitioner or manager at the facility) is required to perform the duties of the Responsible Person as described in the Procedures.

In implementing this Policy, district/service managers and directors, and the designated Responsible Person, must ensure that a health worker operating under this Policy is aware of their responsibility to deliver the intervention in accordance with sections 2.3 and 2.4 of the Take Home Naloxone Procedures.

District/service managers and directors, and the designated Responsible Person, must ensure that naloxone is supplied appropriately. In Local Health Districts and the Justice Health & Forensic Mental Health Network, naloxone is obtained from the Pharmacy Department to the service in accordance with *NSW Health Medication Handling in NSW Public Health Facilities* (PD2013_043). Local Health District Pharmacies will provide naloxone to these services using imprest stock procedures. The Registered Nurse or Manager in charge of the unit is responsible for ordering and storage of imprest stock medications. Responsibility can be delegated to an appropriately authorised person where no Registered Nurse is employed in the service – such as may occur with a Local Health District-employed NSP manager under an HSM award (S 6.1, PD PD2013_043).

In the St Vincent's Health Network, naloxone is obtained from a Health Network pharmacy.

In the MSIC, naloxone is obtained from a licensed pharmaceutical wholesaler.

District/service managers and directors, and the designated Responsible Person, must ensure that naloxone is stored in locked cupboards with restricted access by credentialed health workers and the Responsible Person only. The manufacturer's original packaging must be used.

Dispensing labels must be supplied by the pharmacy department. Dispensing labels may be affixed by the credentialed health worker, if the local Drug & Therapeutics Committee has approved this procedure. Labelling requirements are described further in Section 2.3.6 of the Procedures.

District/service managers and directors, and the designated Responsible Person, must ensure that relevant information is supplied with the naloxone, including the Consumer Information Sheet appropriate to the supplied naloxone product.

In public health facilities, all records relating to the supply of medication must be retained in accordance with the *State Records Authority General Retention and Disposal Authority for Public Health Services: Patient/Client Records* (GDA 17).

In the MSIC, records relating to the supply of take home naloxone under this Policy must be retained in accordance with the *Health Records and Information Privacy Act 2002*.

The Take Home Naloxone Policy and Procedures can be downloaded from:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=pd2020_027

ELECTRONIC MEDICATION MANAGEMENT SYSTEM GOVERNANCE AND STANDARDS (PD2019_050)

PURPOSE

This Policy Directive describes the governance and standards which must be met where an electronic medication management system (eMeds system) is used in a NSW public health facility to prescribe medications for administration to a patient and, where applicable, for pharmacist dispensing.

MANDATORY REQUIREMENTS

All NSW Public Health Organisations must implement this Policy by 31 January 2020 in settings where eMeds systems are used.

IMPLEMENTATION

NSW Ministry of Health:

- Provide the mandatory requirements and standards for the policy.
- Provide the necessary legal instruments under the Poisons and Therapeutic Goods Regulation 2008 to enable eMeds system use under the policy.

Clinical Excellence Commission:

- Support implementation of the policy where applicable to medication safety.

Chief Executives, Health Service Executives, Managers:

- Assign responsibility, personnel and resources to implement the policy.
- Provide line managers with support to implement the policy in their areas.
- Ensure that local policies, protocols and procedures are in place at each facility to support implementation of the policy.

Directors of Clinical Governance:

- With other Executive members, ensure successful implementation of the policy within each Public Health Organisation.

Drug and Therapeutics Committees:

- Develop, approve and oversee the implementation of local policies, protocols and procedures where required.
- Provide local oversight of the safe implementation of this policy.

Electronic Medication Management System Governance and Standards: Procedures

BACKGROUND

About this document

These procedures describe the governance and standards which must be met where an electronic medication management system (eMeds system) is used in a NSW public health facility to prescribe medications for administration to a patient and, where applicable, for pharmacist dispensing.

Key definitions

must	Indicates a mandatory action requiring compliance by staff at public health facilities, in accordance with a legislative requirement and/or a NSW Health policy or directive.
should	Indicates a recommended action that should be followed unless there is a sound reason for taking a different course of action.
administration	The decision to give a medication, giving the medication (such as by mouth, topically or by injection) then documenting that the medication has been given.
authorised prescriber, authorised practitioner	An 'authorised prescriber' in NSW Health Policy Directive *Medication Handing in NSW Public Health Facilities*.
business processes	The procedures for eMeds system use under a local protocol approved by the hospital or health organisation's Drug and Therapeutics Committee.
dispensing	The labelling and supply of a medication, and recording of the supply, by a pharmacist for use by a particular patient on the order of an authorised prescriber. The order may be for patient take-home use of the medication or for administration to an inpatient or outpatient.
electronic medication management system, eMeds system	The software and associated hardware (such as computer terminals and screens) used to create and document the entire medication process from the authorised practitioner's (authorised prescriber's) medication order, to the pharmacist's review of the medication order and supply of medication, to the nurse's record of administration of the medication, and all the processes in between. eMeds systems are sometimes within the electronic medication record (eMR), such as Cerner Millennium eMeds.
prescribing	The decision to treat a patient with a medication and the creation of a medication order in an eMeds system to direct administration or dispensing of the medication. Prescribing in an eMeds system includes continuation, renewal of, or amendment to, a previously valid medication order. Prescribing may be by: a) an authorised practitioner under the Poisons and Therapeutic Goods Regulation 2008, or b) another person authorised under a protocol approved by the health facility's Drug and Therapeutics Committee that accords with requirements under the Poisons and Therapeutic Goods Regulation 2008.

KEY INFORMATION

The Chief Executive must establish a governance process and is accountable for approving and ongoing assurance over the use of the eMeds system to prescribe, administer and dispense (if applicable) medications to ensure the safe use of the system in accordance with the NSW Health eMeds System Standards (in section 3) and must:

- Implement local procedures for assigning roles and access to the system
- Appoint a person responsible for assigning individual access credentials to system users
- Assign accountability for policy compliance to the health facility's Drug and Therapeutics Committee (DTC) or clinical governance committee.

The DTC must approve and regularly review the local business processes on use of the eMeds system, including the identification and management of system risks and issues from data extraction to support quality improvement and medication safety.

The DTC should ensure integrated clinical decision support and medicines information is appropriate and current.

Particular care should be applied where multiple eMeds systems or hybrid systems are used. Risks of duplicate orders, duplicate records of administration or non-contemporaneous orders must be managed through the local business processes.

The eMeds system use should conform to the recommendations in:

- The following Australian Commission on Safety and Quality in Healthcare guidelines, as amended from time to time;
    - *'Electronic Medication Management Systems: A Guide to Safe Implementation'* and addendum, *'Electronic Medication Management Systems Business Requirements'*
    - *'National Guidelines for On-Screen Display of Medicines Information'*
    - *'Recommendations for Terminology, Abbreviations and Symbols used in Medicines Documentation'*
- *'Building sustainable governance of electronic medication management: Guiding Principles for Drug and Therapeutic Committees in NSW'* - NSW Therapeutic Advisory Group Inc. and eHealth NSW (2017).
- The eHealth NSW eMeds/eMR Design Standards (at http://ehnsw.sharepoint.nswhealth.net/apps/ClinP-eMedsHub/Pages/Design-standards.aspx).

  Chief Executives may conduct a gap analysis of current system conformance with these recommendations.

Legal and legislative framework

An authorised practitioner under the Poisons and Therapeutic Goods Regulation 2008 (the Regulation) may electronically prescribe medication in an eMeds system that:

- complies with the NSW Health eMeds System Standards (in section 3), and
- is approved for use by the health facility's Chief Executive.

Compliance with this Electronic Medication Management System Governance and Standards Procedure:

- Means use of the eMeds system is an approved form of prescribing under the Regulation.
- Replaces current individual eMeds system approval by the Ministry for Health for use at specified hospitals.

However, eMeds systems that do not comply with these procedures may alternatively be approved by the Ministry of Health on a case by case basis where assurance of patient safety and data security is in place. The Chief Executive may apply for approval to the Chief Pharmacist, NSW Ministry of Health at MOH-PharmaceuticalServices@health.nsw.gov.au.

eMeds systems are generally an end to end digital process. Hybrid systems with paper outputs other than in section 4 (for medication charts) and section 5 (for prescriptions) may require separate approval and mitigation of specific risks.

Approvals have been issued for specific hospitals or Local Health Districts and include the eMeds functionality in Cerner Millennium, DXC MedChart, eRIC (Intensive Care) and ARIA, CHARM and MOSAIQ oncology systems. These approvals will remain in place until 31 January 2020 to enable transition arrangements if required.

Exemptions to the Regulation are in place to exempt pharmacists from marking dispensed prescriptions "Cancelled".

System approval under the NSW Health eMeds System Standards does not include the keeping of a Schedule 8 drug register in electronic form (including those in Opioid Treatment Program electronic recording systems).

NSW HEALTH EMEDS SYSTEM STANDARDS

Standard	Notes on Compliance
1) Use of the electronic medication management system and associated business processes must be under the governance of the health facility's Drug and Therapeutics Committee or other delegated clinical governance committee which should include expertise in medication safety, quality use of medications and clinical informatics.	
2) Each system user must be assigned individual access credentials, secured by at least one method of authentication, which identifies them as an authorised user of the system. Authorised users must keep their access credentials confidential and secure.	
3) Together the system and associated business processes must restrict access by each authorised user to roles of prescribing, administration and dispensing (if applicable) permitted: a) under the Poisons and Therapeutic Goods Regulation 2008 (where relevant), and/or b) in accordance with any practice conditions imposed by the user's place of employment.	The system must allow prescribing by users other than an authorised prescriber, for example under a Standing Order, as nurse-initiated medication and for radiopharmaceuticals, contrast and Total Parenteral Nutrition. The business processes should ensure compliance with health practitioner registration endorsements and practice restrictions.
4) The system must allow for the administration and dispensing (if applicable) of medication prescribed verbally (face to face or by telephone) or by facsimile or electronic mail.	
5) The system and associated business processes must assure the identity of the authorised user for transactions involving prescribing, administration and dispensing (if applicable) of a medication.	
6) The system and associated business processes must ensure that an electronic medication order is created and presented in such a manner that the receiving user can be confident of the validity and currency of the order.	Quality assurance processes must be in place to ensure that medication prescribing data elements, such as in medication order sentences and order sets, are accurate.

7) The system must support co-signing of records of prescribing, administration and dispensing (as applicable) where required under Regulation, policy or associated business processes.	Includes witnessing of medication administration.
8) The system must display sufficient patient identifiers, including the patient's name and date of birth, to ensure that the user can verify the identity of the patient for each prescribing, administration and dispensing (as applicable) transaction.	
9) The system and associated business processes must ensure the quantity of medication prescribed and intended to be dispensed by a pharmacist is documented in a manner that prevents accidental or intentional dispensing in excess of the quantity prescribed.	Where the medication order is visible to multiple dispensing sites this may be achieved via an appropriately configured prescription exchange service that prevents dispensing medication in excess of the amount prescribed.
10) Records of prescribing, administration and dispensing (as applicable) created by an authorised user must be securely stored under that person's identity and readily visible in the system user interface to other authorised users, including any amended records.	
11) The system and associated business processes must ensure that administration or dispensing (as applicable) are not undertaken in excess of twelve months from the date of prescribing.	Medication order renewal or review constitutes prescribing when documented in the system with the date and time the action occurred. Prescriptions for dispensing Schedule 4 Appendix D and Schedule 8 medications for patient take home are only valid for six months.
12) All current records and relevant ceased records (as appropriate in the circumstances), of prescribing and administration of medication, and any associated records, must be retrievable during system downtime.	
13) Appropriate, documented downtime procedures must be in place to ensure accurate and safe prescribing and administration of medication during and after system downtime to ensure continuity of care. The procedures must be reviewed regularly, rehearsed and available to authorised system users.	
14) All records of prescribing, administration and dispensing (if applicable) of medication, and any associated records, must be retained for the periods required under legislation and NSW Health policy, as amended from time to time.	
15) All records of prescribing, administration and dispensing (if applicable), and any associated records, must be available in a timely manner to a person eligible under legislation or NSW Health policy to inspect such records, including an inspector appointed under section 42 of the Poisons and Therapeutic Goods Act 1966.	

16) The prescribing data elements required for a valid medication order are: a) the patient's name, date of birth and unique identifier(s) b) the authorised prescriber's name c) the medication's active ingredient/s and/or brand name (where approved for use at the health facility) and (if applicable) the strength and dose form d) adequate directions to administer the medication, being; i) the dose, including when the dose may be varied ii) the frequency and, as applicable, the date and times for administration iii) the route for administration, including where this may be varied e) the amount of medication prescribed, being; i) for medication administration to patients at the health facility (inpatients or outpatients); a. the number of doses, or b. the intended duration of treatment (which may be until discharge for an inpatient), or c. the date and time when prescribing review is required (either nominated by the prescriber or as a function of the system as described in the business processes) ii) for pharmacist dispensing for administration to patients at the health facility (inpatients or outpatients); a. the number of doses, or b. the amount determined by the pharmacist under the business processes iii) for pharmacist dispensing for patient take-home use; a. the number or doses, or b. the intended duration of treatment, or c. the amount determined by the pharmacist under the business processes f) the date and time of prescribing g) where applicable, the date and time the previous order for the medication is ceased.	For a 'when required' ('prn') medication, adequate direction for use should include: • the maximum individual dose • the frequency for administration • the maximum daily dose. The business processes may limit the amount the pharmacist should dispense. The pharmacist may dispense any reasonable amount up to that permitted by the valid medication order. The quantity of medication dispensed for inpatients on discharge may be limited under the local business processes.

USE OF PRINTED (PAPER) MEDICATION CHARTS

Printed (paper) medication charts created using an eMeds system to direct medication administration and dispensing must be approved by the health facility's Drug and Therapeutics Committee. This includes use of locally approved standard medication order sets (medication regimens) printed on a paper medication chart.

Printed medication charts created using an eMeds system may also be used in the following circumstances:

- For patient transfer, where printed by a system user assigned responsibility under the business processes
- For eMeds system downtime – see Standard 13 in section 3, where printed by a system user assigned responsibility under the business processes. Note: a detailed assessment and heuristic review of the medication charts recommended for unplanned downtime (724 Downtime Viewer Version 5.3 and Version 5.7) from the Cerner eMR in NSW has been completed. This assessment is available from the eMR Connect Program (email: HSNSW-emmenquiries@health.nsw.gov.au).

Together the system and business processes must ensure the printed medication chart orders are accurate, current and complete, and with only one version in use. Business processes must also ensure the printed medications chart is retained in the patient's medical record.

USE OF PRINTED (PAPER) PRESCRIPTIONS

As an alternative to traditional handwritten prescription an authorised prescriber may generate, print and sign in handwriting a paper-based prescription created using an eMeds system in the following circumstances:

- To prescribe a medication for dispensing in a hospital pharmacy in accord with the business processes
- When the eMeds system does not comply with Standard 9 in Section 3 and therefore there is a risk of accidental or intentional dispensing in excess of the quantity prescribed
- To prescribe a medication in the category Section 100 Highly Specialised Drugs to meet Pharmaceutical Benefits Scheme (PBS) requirements to be eligible for Commonwealth reimbursement
- To prescribe a medication for dispensing in a community pharmacy, including for public health facility aged care residents (residential care and flexible care residents under the Commonwealth Aged Care Act 1997).

Standards for printed paper prescriptions

Where the eMeds system is used to create a paper prescription for dispensing of a medication by a hospital or community pharmacist for patient take-home use, the prescription must comply with the NSW Ministry of Health TG184 '*Criteria for Issuing Non-handwritten (Computer Generated) Prescriptions*' (available at http://www.health.nsw.gov.au/pharmaceutical/Documents/prescriptions-nonhandwritten.pdf).

General criteria

Under the criteria in TG184 the following mandatory prescribing data elements must be created with and printed by the eMeds system:

- The date on which the prescription is issued.
- The name of the patient (including given name, or initial letter).
- The full residential address of the patient.

- The name of the substance or the preparation containing it, including the strength where more than one strength is available.
- The quantity to be dispensed in figures (numerals) and, for a Schedule 8 medication, in words (Note: there is an exemption for a Schedule 8 medication where the prescription is dispensed at the hospital pharmacy).
- Adequate directions for use.
- The number of repeats authorised if repeats are ordered.
- The interval for repeats if required by legislation (Schedule 4 Appendix B and Schedule 8 medications) or otherwise deemed appropriate by the prescriber.

The eMeds system must require:

- The prescription to be created by the prescriber only.
- The prescriber to sign, in their own handwriting, the paper prescription form as near as practicable below the last item prescribed on the form.
- The prescription to be printed on a form which is pre-printed with the name and address and contact telephone number of the prescriber **OR** which the system prints on the prescription **OR** which is pre-printed with at least the address and contact telephone number of the practice/hospital **and** the system individually prints the name of the prescriber on the prescription during generation.
- Either a statement to be printed on each prescription form indicating the total number of items prescribed on that prescription form, **or** any unused area on the prescription form to be scored, hatched or marked to prevent any other item being printed in that area.
- A number which uniquely identifies the prescription **OR** which uniquely identifies the medication printed on the prescription and which can be related to the clinical or prescription record of the patient.
- When the patient is an infant or a child under the age of twelve, the age of the patient to be included on the prescription.
- When the prescriber requires a dose that is less than 1mL and that dose is recorded as a decimal value, the dose to be printed with a leading zero (that is, 0.3mL rather than .3mL).
- The particulars of any prescription issued to be included in the clinical or prescription record of the patient, retained for at least seven years from the date on which the prescription was created and accessible when required.

Additional requirements for Schedule 8 medications

A prescription for a Schedule 8 medication must not include any other medication.

The eMeds system must prompt the prescriber to hand write the mandatory data elements other than the date and the patient's name and address, namely:

- The name of the substance or the preparation containing it, including the strength where more than one strength is available.
- The quantity to be dispensed in figures (numerals) and words (Note: there is an exemption for a Schedule 8 medication where the prescription is dispensed at the hospital pharmacy).
- The directions for use.
- The number of repeats authorised if the prescription is to be dispensed more than once and, if repeats are ordered, the time interval for repeats.

General notes

- The mandatory prescribing data elements produced in accordance with the criteria must be issued without alteration to ensure both that the system record is consistent with the prescription and that the dispensing pharmacist will not be concerned about either accuracy or possible imposition.
- Any additional requirements of the Commonwealth Government PBS must be observed.
- Schedule 4 medication prescriptions issued by dentists, optometrists or podiatrists must be endorsed "For dental treatment only", "For optometrical treatment only" or ‘For podiatry treatment only” respectively. Schedule 8 medication prescriptions issued by dentists must be endorsed "For dental treatment only".
- A prescription duplicate must not be issued other than for a PBS medication (Note: The prescriber must destroy a duplicate prescription containing only PBS medication which is printed by a system default).
- For a PBS medication issued with a prescription duplicate the mandatory prescribing data elements must only be handwritten on the prescription marked to be retained by the dispensing pharmacist.
- Where a system for producing non-handwritten prescriptions does not satisfy the criteria in TG184 the individual approval of the Secretary, NSW Health must be sought.

NEW REPORTING REQUIREMENTS FOR THE *OPIOID OVERDOSE RESPONSE & TAKE HOME NALOXONE* INTERVENTION (IB2020_004)

PURPOSE

This Information Bulletin is relevant to all services that supply naloxone to clients in compliance with the *NSW Opioid Overdose Response & Take Home Naloxone Policy Directive* (PD2019_036). This includes Alcohol and Other Drugs services, Needle Syringe Programs and a range of other services.

The Australian Government is conducting a take home naloxone access pilot through the Pharmaceutical Benefits Scheme ('PBS pilot'). The PBS pilot subsidises the full cost of take home naloxone supplied to people at risk of experiencing or witnessing opioid overdose.

The PBS pilot runs from **1 December 2019 to 28 February 2021** and NSW is participating. From **1 March 2020**, NSW Health services supplying take home naloxone for ORTHN interventions can access naloxone through the PBS pilot for free. A PBS prescription is not required.

This Information Bulletin outlines how ORTHN sites must collect and provide legally mandated data for take home naloxone supplied during the PBS pilot.

The information bulliten in full is available at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=IB2020_004

328(03/03/20)

PHARMACY DEPARTMENT REIMBURSEMENT AND DATA COLLECTION DURING PBS-SUBSIDISED NALOXONE PILOT (IB2020_005)

PURPOSE

The Australian Government is conducting a pilot under Section 100 of the Pharmaceutical Benefits Scheme (PBS) for subsidised supply of take home naloxone to people at risk of experiencing or witnessing opioid overdose. NSW is participating in the pilot.

During the pilot period of **1 December 2019 to 28 February 2021**, PBS-listed naloxone medicines (all formulations) indicated for the reversal of opioid overdose have S100 listing under the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (*Special Arrangement*) and can be supplied or dispensed without a PBS prescription and with no patient co-payment. These conditions are extended to NSW public hospitals despite NSW not currently being a signatory to the Pharmaceutical Reform Agreement.

This Information Bulletin is relevant to pharmacy departments that purchase and supply Nyxoid® and Prenoxad® as imprest, ward or clinic stock for NSW Health ORTHN sites.

An ORTHN site is a NSW Health service delivering take home naloxone interventions in compliance with the *NSW Opioid Overdose Response & Take Home Naloxone Policy Directive* (PD2019_036).

This Information Bulletin outlines how hospital pharmacy departments may seek reimbursement for naloxone supply and how legally mandated data must be collected and provided for naloxone supplied or dispensed as part of the pilot.

The information bulliten in full is available at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=IB2020_005

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TAKE HOME NALOXONE SUPPLY BY HOSPITAL UNITS (IB2020_036)

PURPOSE

NSW is participating in the Australian Government Section 100 Pharmaceutical Benefits Scheme (PBS) pilot for subsidised supply of take home naloxone to people at risk of experiencing or witnessing opioid overdose.

This Information Bulletin provides guidance to pharmacy departments, emergency departments (EDs), pain clinics and other hospital units wishing to supply PBS-subsidised naloxone for patients on discharge.

For supply of naloxone by 'credentialed health workers' in alcohol and other drugs and needle syringe program settings, please refer to NSW Health Policy Directive *Take Home Naloxone* (PD2020_027), Information Bulletin's *New Reporting Requirements for Opioid Overdose Response and Take Home Naloxone Intervention* (IB2020_004) and *Pharmacy Department Reimbursement and Data Collection During PBS-Subsidised Naloxone Pilot* (IB2020_005).

The information bulliten in full is available at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=IB2020_005