Electronic Medication Management System Governance and Standards

Summary Policy on governance and standards for electronic medication management system use in public health facilities.

Document type Policy Directive

Document number PD2019_050

Publication date 10 October 2019

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Review date 10 October 2024

Policy manual Not applicable

File number H19/629

Status Active

Functional group Clinical/Patient Services - Information and Data, Pharmaceutical

Applies to Ministry of Health, Public Health Units, Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health Pathology, Public Health System Support Division, Cancer Institute, Government Medical Officers, Community Health Centres, NSW Ambulance Service, Dental Schools and Clinics, Public Hospitals

Distributed to Ministry of Health, Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Health Associations Unions, Tertiary Education Institutes

Audience All Staff across Ministry of Health and NSW Health Organisations

Secretary, NSW Health

POLICY STATEMENT

ELECTRONIC MEDICATION MANAGEMENT SYSTEM GOVERNANCE AND STANDARDS

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.

REVISION HISTORY

Version	Approved by	Amendment notes
October-2019 (PD2019_050)	Secretary, NSW Health	New Policy Directive

ATTACHMENT

Electronic Medication Management System Governance and Standards: Procedures

Electronic Medication Management System Governance And Standards

NSW GOVERNMENT

PROCEDURES

Issue date: October-2019

PD2019_050

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1 BACKGROUND

1.1 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.

1.2 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.

2 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.

2.1 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).

3 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	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.

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.	The quantity of medication dispensed for inpatients on discharge may be limited under the local business processes.

4 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.

5 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).

5.1 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).

5.1.1 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.

5.1.2 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.

5.1.3 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.