Medicines Policy (DQ136)

The overarching policy for Medicines Management

Overview

What is this policy?

This policy is designed to ensure that medicines are managed safely and securely, adhering to medicines and Controlled Drugs legislative requirements, Care Quality Commission (CQC) standards and clinical recommendations within We Are With You.

The CQC requires that independent medical agencies establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner.

Regulation 11(3)(c) sets recommendations for the Standard Operating Procedures (SOPs) an organisation must have in place relating to the prescribing, supply and administration of CDs including clinical monitoring of those who have been prescribed CDs.

This regulation is met by:

- ➔ Management of Prescriptions Policy (DQ136.1)
- ➔ Storage and Disposal of Controlled Drugs (DQ136.2)
- ➔ Prescribing Controlled Drugs Policy (DQ136.3)
- ➔ Dispensing and Administering Controlled Drugs Policy (DQ136.4)
- ➔ Medication and Controlled Drug Incident Reporting Policy (DQ136.5)
- ➔ Storage of Medication (DQ136.6)

When to use this policy

All staff working within We Are With You who are involved with the use of medicines must familiarise themselves with this policy and the supplementary medicines

management policies and procedures and must complete all modules of the Medicines Management e-Learning via the Learning and Development Gateway.

What’s included in this policy

This policy was last updated: Feb 2020

This policy will next be updated: Feb 2022

1.0 PATIENT SPECIFIC DIRECTIONS (PSD) AND PRESCRIPTIONS

1.1 A PSD is a written instruction from an independent prescriber (doctor, dentist or independent nurse prescriber) to another healthcare professional to supply and/or administer a medicine directly to a named client. PSDs are used once a client has been assessed by a prescriber and that prescriber (doctor, dentist or independent prescriber) instructs another healthcare professional in writing to supply or administer a medicine directly to that named client or to several named clients.

1.2 A prescription is a written direction from a registered prescriber for a specific medication to be administered or to be supplied to a named specific individual. It is a form of PSD.

1.3 As a PSD is individually tailored to the needs of a single client, it should be used in preference to a PGD wherever appropriate

2.0 PATIENT GROUP DIRECTIONS (PGD)

2.1 PGDs are defined as written instructions for the supply or administration of medicines to groups of clients who may not be individually identified before presentation for treatment.

2.2 PGDs are not a form of prescribing but provide a legal framework for the supply and/or administration of medicines by a range of qualified healthcare professionals such as nurses and pharmacists.

2.3 It is vital that all users of PGDs are fully competent and trained in their use. For further information please refer to DQ393 PGD Development

3.0 ADMINISTRATION OF MEDICINES

For further information refer to DQ136.4 Dispensing and Administering CDs

3.1 Administration refers to the act of selecting a dose of medication and placing it in the hand of the patient or giving it via injection e.g. immunisations

3.2 The authorisation of a suitably qualified practitioner must be obtained before medicines can be administered to patients. Authorisation will usually be by one of the following means:

- An instruction written on the appropriate prescription by a medical practitioner or a registered non-medical prescriber. If there is any doubt

about the legibility or details of the prescription the prescriber must be contacted for further clarification. Note that a medicine administration record (MAR) sheet is not an authority to administer

- In exceptional circumstances, where delay in administering medication would compromise patient care, by verbal order from a prescriber. Note that the prescriber must provide a prescription or amend the drug chart as soon as possible, ideally within 24 hours. A note of the administration including the dose, strength and quantity administered as well as details of who gave the verbal order and who administered the medication must be made in the client's notes. **Verbal orders must not be used for schedule 2 controlled drugs.**
- In accordance with a PGD

Exception: Emergency administration of Naloxone and Adrenaline for saving life.

3.3 Except where indicated in the We Are With You procedures, a second nurse/witness is needed for the administration of:

- Controlled Drugs (CDs)
- Injections

3.4 The identity of the patient must be secured before the administration of medication using a legally acceptable form of photographic ID.

3.5 The allergy status of the patient must be documented and known before the administration of medication.

3.6 All prescriptions must be legally valid and clear before proceeding with administration. The prescriber signature must be checked against a complete list or register of prescribers held in the service or prison

3.7 For administration in prison settings please refer to National Clinical Guidelines for Substance Misuse Prescribing and Drug Treatment in the Adult Prison Setting DQ200

4.0 DISPENSING OF MEDICINES

For further information refer to DQ136.4 Dispensing and Administering CDs

4.1 Dispensing of Medication is the selection of medicine from stock or issue against a valid prescription, which is then "dispensed" into an appropriate container for taking away, which is then labelled in accordance with legal requirements.

4.2 The dispensing of medicines must not be carried out by staff other than in Service Delivery and Clinical Governance Group (SDCGG) approved services

providing opiate substitution/withdrawal medication which must comply with DQ136.4 Dispensing and Administering CDs

4.3 The issue of specified pre-dispensed packs e.g. take-home naloxone is not considered dispensing, it is the issue of a pre-packed medicine and must be performed in line with the specific criteria as set out within DQ227 (Naloxone Supply and Emergency Use)

5.0 TRANSPORT OF MEDICINES (WITHIN WE ARE WITH YOU)

5.1 All medication stock items must be transported to and within We Are With You sites by people contracted to undertake this work, providing that the required insurance and contract agreements are in place for them to do so. This must be performed in validated transport boxes

5.2 In vaccination clinics, staff may be required to vaccinate in a location, which is removed from the medicines fridge and therefore are unable to access stock. In these circumstances then validated cool boxes must be used to temporarily store and transport vaccines for the duration of the clinic. The procedure is outlined in Storage of Medication DQ136.6.

5.3 In exceptional circumstances, staff may be required to carry medicines that have been prescribed for named patients. The drugs must be transported out of sight in a locked car from the dispensing pharmacy directly to the patient. If this pertains to CDs, refer to DQ136.4 Dispensing and Administering CDs

5.4 Medicines must not be left unattended or unsecured at any time during transport.

5.5 When medicines are received at their final destination, they must not be left unattended or unsecured. They should be handed to a registered nurse in charge, and locked away in a medicine cupboard at the earliest opportunity or given immediately to the patient/carer.

5.6 All medicines transported from local pharmacy providers to the services must be carried in designated sealed containers.

5.7 In the interest of safe practice it is recommended that the procedure and proforma utilised within DQ136.2 Storage and Disposal of CDs should be used for the transport of any medication within We Are With You except for transporting stock vaccines as outlined above.

6.0 PATIENTS OWN MEDICINES

For prison services please refer to National Clinical Guidelines for Substance Misuse Prescribing and Drug Treatment in the Adult Prison Setting DQ200

6.1 All service staff must **not** accept any medication from patients to store on site or on their person on the patient's behalf. The only exception to this is in residential sites where patient's own medicines must be kept in a locked treatment cupboard in a secure room and a record kept of balance, or in prison services.

6.2 This includes custody of medication to process for destruction as the patient must utilise the community pharmacy for this service

6.3 This includes the custody of compliance aids or dispensed medication in order to support daily medicines taking. The service must use the facilities of local community pharmacies.

7.0 STAFF MEDICINES AND RELATED PRODUCTS FOR PERSONAL USE

7.1 During the course of their working hours, staff and volunteers may have in their own possession for personal use: medication, medicinal related items, vitamins and complementary therapies.

7.2 Irrespective of whether these items are prescribed by a healthcare professional or purchased from a pharmacy, retail outlet or other appropriate supply chain under NO CIRCUMSTANCES should any item be given to clients or their relatives/carers for their own personal use.

7.3 Where staff need to have medicines or related products in their possession careful consideration should be given to the item and any associated risks. The minimum quantity should be carried for the working day.

7.4 Where items are prescribed these must be in the original packaging and have a pharmacy label showing the item is prescribed and issued for that staff member.

8.0 MEDICATION ERRORS

DQ136.5 Medication Incident Reporting describes the actions taken following the discovery of medication error. This procedure is applicable to all medication errors

8.1 A medication error is defined as a preventable incident associated with the use of medicines, which may put a patient at risk. Such incidents may be

related to any of the steps in the medicine use process. This includes prescribing, dispensing and administration of the medicine and the transfer of information.

8.2 For every medication error identified an incident form must be completed as per the incident reporting policy.

8.3 All medication incidents are reviewed as below:

Service Level	
Senior Pharmacist/Pharmacy Tech	**Clinical/Medical Lead**
Review all Meds Man related incidents	Review all incidents
Review critical incidents (≥ 15)	Chair service Clinical Governance (CG) meeting
Attends service CG meeting	Review deaths and allocate initial Structured Judgement Review (SJR) score
	Complete service level Incident Reporting Form (IRF)
Regional Level	

Lead Clinical Pharmacist (LCP)	Lead Clinical Nurse (LCN)
Overview of Meds Man incidents (≥ 10)	Overview of all incidents (except Meds Man) ≥ 10
Attends service CG meetings where additional support is required	
Overview of all deaths to apply SJR scoring (independently)	
LCN and LCP review all incidents (≥ 10) and deaths (to agree SJR score) prior to CG section of Regional Hub meeting (this may include the DoP/senior pharmacist)	
Deputise for LCN at Regional Hub meeting	Chair CG section of Regional Hub meeting
Complete regional level IRF (LCP to complete if LCN chairs and vice versa) Include case study/discussion of specific incidents extract for learning	
National Level	
Director of Pharmacy	**Director of Nursing**
Attendance at CIRG (review of critical incidents ≥ 15)	
Attendance at DRDP (review of preventable deaths)	
Oversight of all incidents (safety net)	
	Review all safeguarding incidents

8.4 Incidents that require critical and more urgent action must be shared with the We Are With You CDAO and the NHSE CDAO promptly (outside of the regular CDLIN) as well as being captured in the regular occurrence reports (see section 11 for more information).

8.5 Near Misses

- We Are With You encourages the reporting of 'near misses'.
- A near miss is defined as a medication error that takes place up to and including the point at which the medication is handed over to the patient but is not administered to a patient (where a critical incident could have occurred but did not because it was detected before administration to the patient).
- The reporting of 'near misses' will assist We Are With You in highlighting areas of risk to patients and staff and help to identify training needs.
- Near misses should be reported in the same way as other medication errors. For further detail please refer to DQ136.5 Medication Incident Reporting

9.0 MEDICAL GASES

9.1 All medical gases are licensed medicines, and as such are subject to the Medicines Act, and must be treated in the same way as any other medicines.

9.2 Staff must not prescribe, administer or supply any medical gases.

10.0 CLINICAL TRIALS

10.1 Clinical trials can be for licensed medicines or for medicines being tested before the issue of a product license by the MHRA.

10.2 Staff must not run or involve clients in clinical trials (for licensed or new medication) unless permission has been granted by the Executive Medical Director.

11.0 CONTROLLED DRUG ACCOUNTABLE OFFICER (CDAO) AND LOCAL INTELLIGENCE NETWORKS (LINs)

The 2013 CD Regulations carried forward a number of measures from the 2006 Regulations to underpin the arrangements to ensure the safe management and use of CDs and one of these requirements was the creation of Local Intelligence

Networks (LINS). These were established by NHS England Local Area Teams and exist to provide a network for sharing information. Every region of We Are With You must have a nominated Local Accountable Person (LAP) who provides information for external monitoring to the LIN and liaises with the We Are With You CDAO and the local LIN.

The CDAO must be a senior manager of We Are With You or answerable to such a senior manager who does not routinely prescribe, supply, administer or dispose of controlled drugs as part of their duties. Whilst the CDAO delegates some aspects of the role, the overall responsibility cannot be delegated

11.1 The CDAO for We Are With You is the Director of Pharmacy

11.2 The We Are With You CDAO must ensure there is appropriate information and training, monitoring and auditing associated with policies for staff handling CDs and CD stationary. They are responsible for the monitoring of the safe use and management of CDs in We Are With You and managing any complaints or concerns around CDs.

11.3 The We Are With You CDAO is responsible overall for ensuring that We Are With You has appropriate arrangements for securing the safe destruction and disposal of CDs (see DQ136.2 Storage and Disposal of Controlled Drugs)

11.4 We Are With You CD policies (Management of Prescriptions Policy (DQ136.1), Storage and Disposal of Controlled Drugs (DQ136.2), Prescribing Controlled Drugs Policy (DQ136.3), Dispensing and Administering Controlled Drugs Policy (DQ136.4) and Medication and Controlled Drug Incident Reporting Policy (DQ136.5)) are monitored internally at three levels:

1. Self declaration Medicines Management Surveys submitted by service managers
2. National audit of the service performed by the clinical audit / medicines management teams
3. Incidents being reported via Critical Incident Reporting Group (CIRG) reviewed nationally and shared locally by the local clinical governance hubs

11.5 Due to the geographic scope of the role it is not necessary for the CDAO personally to undertake all the operational tasks associated with the role requirements at a regional or area level. Therefore, the regional managers for We Are With You must ensure that a suitably briefed senior representative of We Are With You act as the Local Accountable Person (LAP) and attend on behalf of We Are With You CDAO. They must be a registered healthcare professional and/or manager with assigned delegated duties at a local level.

11.6 The LAP is responsible for ensuring that occurrence reports, or 'nil reports' where no CD occurrences have been reported, are submitted in time to the LIN. The LAP is also accountable for exception reports outside of the quarterly cycle that require rapid response and must be reported by the LAP to the LIN. The occurrence reports will be reviewed at the LIN meeting, in accordance with LIN procedures, to cross reference concerns between

organisations and to ensure appropriate actions are taken by each organisation. Following LIN meetings, the LAP must ensure the We Are With You CDAO and the We Are With You central governance team are provided with the relevant communications and follow up reports and follow-up from the LIN.

11.7 Additional functions of the LAP are:

- Ensure LIN knows who is attending (LAP or deputy)
- Ensure Clinical Incident Administrator contacted to populate the Occurrence report
- Where no incidents then complete a "non-occurrence report"
- Provide CD audit of procedures as required by the LIN
- Send Director of Pharmacy papers & completed reports
- Information from the CDLIN/NHSE must additionally be shared via the LAP internally, and include the We Are With You CDAO, especially if feedback may influence wider organisational learning
- For serious incidents and concern the LAP must share the information more urgently outside of the regular LIN meeting. This will be in addition to raising an Critical Incident Report and informing the We Are With You CDAO.

- In cases of serious incidents or concerns the LIN CDAO may make recommendations as to what actions are to be taken to protect the safety of patients and the general public. The lead NHS CDAO will be responsible for taking reasonable steps to protect the safety of patients or the public, including referring the matter as appropriate to the individual's regulatory body or the police. This will be in collaboration with the We Are With You CDAO.

11.8 Where CD Audits are required, the operational manager must liaise with the Medicines Management Team and Director of Pharmacy (CDAO)

11.9 The list of Local Accountable Persons in We Are With You and their corresponding LIN and CDAO for the Local Area Teams is held nationally by the Medicines Management team who also maintain the LAP/CDLIN register and must be notified immediately of any changes.

11.10 The relevant individual (RI) is any We Are With You employed Registered Healthcare Professional staff member handling Controlled Drugs and Controlled stationary who has received information, education and/or training to the We Are With You CD SOPs to enable them to carry out their responsibilities. This can include anyone prescribing, supplying, administering, transporting or disposing of CDs.

12.0 FORMULARY

12.1 The purpose of the Formulary (DQ231) is to ensure:

- Prescribing is safe, cost effective and clinically appropriate
- Patients are supported to access NICE recommended medicines
- Clarity on what is considered formulary and off-formulary prescribing

12.2 The group responsible for reviewing any new formulary requests for We Are With You is the SDCGG

12.3 Where discrepancies exist from the We Are With You National Formulary and the Local CCG Formulary then We Are With You will liaise with the local medicines management team and commissioners and agree a process locally

12.4 It is the responsibility of the Medicines Management Team and the SDCGG to monitor prescribing against the formulary.

13.0 CLINICAL GOVERNANCE - MONITORING AND POLICY REVIEW

13.1 All staff when handling CDs must ensure minimal disruption to minimise errors.

13.2 Performance of Registered Healthcare Professionals (RHPs) RIs and all other staff are scrutinised and monitored. Premises are also inspected. These processes are outlined below:

- All services must complete the annual Medicines Management Audit which checks compliance. Where non-compliances are identified then Local Action Plans must be implemented to ensure progress towards compliance.
- All medication incidents involving CDs, even if near misses must be reported to the MSO, CDAO and the CIRG for incident overview as outlined in these CD SOPs to detect trends.
- All RHPs are monitored against the criteria outlined in Maintaining High Professional Standards Policy (DQ179). Where standards are not maintained then individual performance plans must be implemented to support the individual.
- All prescribers are monitored by review of the prescribing data from the We Are With You prescribing systems, ePACT and spot check audits of high risk areas of prescribing. This is performed by the Director of Pharmacy/CDAO and the Medicines Management Team.
- Concerns regarding RI and staff reported may be investigated and will include actions that have arisen as a consequence of following or not, the requirements set out in an SOP which may include implementation of the Disciplinary Policy (DQ008), informing the professional body where relevant, re-training or updating of policies depending on the level and severity of the concerns.

13.3 **Local Protocols:** All We Are With You services must adhere to these CD policies to ensure they are working to the current legislation and best practice. However it is also recognised that there may be exceptional circumstances in some services that lead to a non compliance. In these circumstances the service must contact the Medicines Management team for discussion and where it is deemed appropriate a local protocol will be developed by the Medicines Management team in conjunction with the service. Any local protocols must go through the approval process via the CGG. A list of these is maintained by the Director of Pharmacy.

14.0 THE PHARMACEUTICAL INDUSTRY

Due to the multidisciplinary prescribing model within We Are With You and to ensure conduct is transparent, declarations of interest should be raised appropriately as per the Anti Bribery and Transparency Policy (DQ169).

14.1 Within We Are With You, it is acknowledged that conflicts of interest can arise in medicines management practice due to:

- Pharmaceutical Companies having formal partnership arrangements with We Are With You at director level
- Pharmaceutical Companies funding We Are With You prescribers attendance and/or speaking at both national and international conferences
- Pharmaceutical Companies establishing local training meetings and events for We Are With You
- Pharmaceutical companies making payments to We Are With You prescribers as expert consultants
- Pharmaceutical companies providing promotional gifts to We Are With You services

14.2 It is the responsibility of Line Managers to ensure that acceptance of any invitations to drug company sponsored educational events resulting in time taken away from work has followed the internal procedure outlined in the Anti Bribery and Transparency Policy (DQ169). Managers should communicate any such invitations with the Director of Pharmacy to ensure there is no conflict or duplication.

14.3 In addition to the monitoring of declarations of interest as outlined in the Anti Bribery and Transparency Policy, attendance of RHPs at drug company sponsored events is monitored nationally via the SDCGG

14.4 In the event of Pharmaceutical Companies offering medicines related incentives, e.g. rebates, the Director of Pharmacy and Medicines Management Team must be involved in the decision making process.

15.0 PROCESS OF IMPLEMENTATION

The process of implementation of the Medicines Code occurs at various levels within We Are With You.

15.1 The Medicines Code is ratified by the Clinical Policy and Guideline Review group

15.2 The procedures sitting underneath this main policy for medicines (except CD Procedures which are applicable to all services) may be agreed for services at a local level however must comply with this and supplementary medicines policy/procedures outlined in the introduction.

15.3 CD procedures are nationally established by We Are With You and must be applied by all services involved in storage, handling and use of CDs

15.4 The policy and all updates are disseminated via We Are With You clinical governance communications bulletin and are posted on We Are With You intranet.

15.5 We Are With You provides additional training to the Medicines Policy and supplementary policies /procedures via an e-learning module and face to face learning as required.

15.6 New staff must be made aware of the policy via the We Are With You induction system.

16.0 MONITORING ARRANGEMENTS AND MEDICINES MANAGEMENT SELF DECLARATION

The compliance and implementation of the policy is monitored via four processes.

16.1 The service audit, which incorporates the medicines management audits, scrutinised by the SDCGG who disseminate information downstream to We Are With You staff through the Clinical Governance bulletin. This ensures that revisions of policy, non compliance and learning is understood and shared

16.2 The We Are With You critical incident review process monitors for medication errors where they are scrutinised by the CIRG who recommend organisational learning to the SDCGG. Any process change and subsequent policy update is addressed via the SDCGG.

16.3 Prescribing data and ePACT data from NHS Business Service Authority monitors the quality of prescribing measuring compliance with the Formulary.

16.4 Medicines Management Self Assessment Declarations

17.0 STANDARDS/KEY PERFORMANCE INDICATORS (KPIs)

17.1 This policy and any linked operating procedures must adhere to CQC Key Lines of Enquiry (KLOE), specifically Standard 4

17.2 The medicines management self declaration surveys, inspection audits and contracting processes define the KPIs applicable to the medicines code to ensure We Are With You:

- Handles medicines safely, securely and appropriately
- Ensures medicines are prescribed and given by people safely
- Follows published guidelines about how to use medicines safely
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18.0 Other relevant policies and guidelines

- DQ231 Formulary
- DQ101 Non-Medical Prescribing Policy
- DQ393 PGD Development Policy
- DQ070 Substance Use on the Premises Policy
- DQ227 Naloxone Supply and Emergency Use
- DQ200 National Clinical Guidelines for Substance Misuse Prescribing and Drug Treatment in the Adult Prison Setting.
- DQ398 Substance Misuse Medication Guidelines
- DQ399 Prescribing and Treatment Review Guidelines

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