HWCGS Care (T/A Segal Gardens)
436 Fleet Lane, Parr, St Helens, nr Liverpool, Merseyside, WA92NH

Review Sheet

Last Reviewed	Last Amended	Next Planned Review
11 Jun '20	11 Jun '20	in 12 months, or sooner as required.

Business impact	**MEDIUM IMPACT** — Changes are important, but urgent implementation is not required, incorporate into your existing workflow.
Reason for this review	Scheduled review
Were changes made?	Yes
Summary:	This policy details the procedure in place to reduce the risk of medication errors, near misses and discrepancies, as well as defining how it responds and learns from medication related incidents. The policy has been reviewed, the Procedure section amended slightly to include reporting of CD errors accordingly to the local NHS Controlled Drugs Accountable Officer. There is also an added hyperlink of associated accessibility to further policies and the inclusion of the CQC 'reporting medicine related guidance' document.
Relevant legislation:	• The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 • Medical Act 1983 • Medicines Act 1968 • The Human Medicines Regulations 2012 • Misuse of Drugs Act 1971 • The Misuse of Drugs (Safe Custody) Regulations 1973
Underpinning knowledge - What have we used to ensure that the policy is current:	• Author: NICE, (2014), *Managing medicines in care homes*. [Online] Available from: https://www.nice.org.uk/guidance/SC1/chapter/1-Recommendations#care-home-staff-administering-medicines-to-residentsCQC [Accessed: 11/6/2020] • Author: Care Quality Commission, (2009), *Regulation 18: Notification of other incidents*. [Online] Available from: http://www.cqc.org.uk/content/regulation-18-notification-other-incidents#full-regulation [Accessed: 11/6/2020] • Author: NHS improvement, (2014), *Improving medication error incident reporting and learning*. [Online] Available from: https://improvement.nhs.uk/news-alerts/improving-medication-error-incident-reporting-and-learning/ [Accessed: 11/6/2020] • Author: Royal Pharmaceutical society, (2018), *Professional guidance on the safe and secure handling of medicines*. [Online] Available from: https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines [Accessed: 11/6/2020] • Author: NICE, (2017), *Managing medicines for adults receiving social care in the community*. [Online] Available from: https://www.nice.org.uk/guidance/ng67 [Accessed: 11/6/2020] • Author: CQC, (2020), *Reporting medicine-related incidents*. [Online] Available from: https://www.cqc.org.uk/guidance-providers/adult-social-care/reporting-medicine-related-incidents [Accessed: 11/6/2020]
Suggested action:	• Encourage sharing the policy through the use of the QCS App

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1. Purpose

1.1 To define medication errors and detail the action required following the discovery of a medication error to ensure Service Users' safety whilst supporting staff. This policy dovetails with CM02 - Overarching Medication Policy and Procedure and any other local contractual policies that may supersede this policy.

1.2 To support HWCGS Care (T/A Segal Gardens) in meeting the following Key Lines of Enquiry:

Key Question	Key Lines of Enquiry
SAFE	S4: How does the provider ensure the proper and safe use of medicines?
WELL-LED	W2: Does the governance framework ensure that responsibilities are clear and that quality performance, risks and regulatory requirements are understood and managed?
WELL-LED	W4: How does the service continuously learn, improve, innovate and ensure sustainability?

1.3 To meet the legal requirements of the regulated activities that HWCGS Care (T/A Segal Gardens) is registered to provide:

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Medical Act 1983
- Medicines Act 1968
- The Human Medicines Regulations 2012
- Misuse of Drugs Act 1971
- The Misuse of Drugs (Safe Custody) Regulations 1973

2. Scope

2.1 The following roles may be affected by this policy:

- Registered Manager
- Other management
- Care staff

2.2 The following Service Users may be affected by this policy:

- Service Users

2.3 The following stakeholders may be affected by this policy:

- Commissioners
- External health professionals
- Local Authority
- NHS

3. Objectives

3.1 There is an open, transparent, just and fair learning culture within HWCGS Care (T/A Segal Gardens). This enables staff to report and record errors, omissions and near misses in a timely manner; and for investigations and identification of the root cause of issues to take place. All staff responsible for any aspect of medication management recognise their role in safeguarding the wellbeing of Service Users at all times.

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4. Policy

4.1 HWCGS Care (T/A Segal Gardens) promotes a culture where staff feel able to raise any concerns to Mr Damian Cummings Gillian Gilmore, in order to provide an effective and safe service.
4.2 The priority of HWCGS Care (T/A Segal Gardens) is to ensure the safety and wellbeing of Service Users, and in the event of a medication error or incident, it will seek immediate advice from the relevant and most appropriate health professionals according to the severity of the incident.
4.3 HWCGS Care (T/A Segal Gardens) actively encourages a sensitive response to medication errors through investigation, taking full account of how the incident occurred and the circumstances surrounding the incident.
4.4 Where applicable, incidents are reported to St Helens and the CQC in a timely manner, and HWCGS Care (T/A Segal Gardens) pays due consideration and compliance to Duty of Candour.
4.5 HWCGS Care (T/A Segal Gardens) uses root cause analysis to ensure that lessons are learned and applied to reducing the risk of reoccurrence. Staff are fully involved in this process and the outcomes are shared with relevant staff at HWCGS Care (T/A Segal Gardens).

5. Procedure

5.1 Reducing the Risk of Medication Errors, Near Misses and Discrepancies

A proactive approach must be taken to identifying where the risks are in relation to medication management, to achieve this, the following principles apply:

- Any member of staff responsible for medication is competent, trained and accountable for their actions as per their code of professional conduct
- Staff feel supported and able to raise concerns directly and in a timely manner. Refer to PM11 - Whistleblowing Policy and Procedure
- Systems and processes for all aspects of medication management are followed as per HWCGS Care (T/A Segal Gardens) suite of medication policies and procedures
- Issues arising from partnership working are managed in a proactive and timely manner
- Staff are aware of and adhere to notifications from national safety alerts and notices (refer to AB32 - Distribution of Safety Alert Broadcasts, Rapid Response Reporting and Safety Notices Policy and Procedure)
- Best practice is followed at all times and staff maintain their knowledge and keep updated with changes (this list is not exhaustive)

5.2 Action to be Taken by a Member of Staff Involved in a Medication Error or Near Miss

The following actions should be taken:

- As soon as the error or near miss is identified, assess the Service User's condition to establish if the Service User has suffered any harm. Refer to CC20 - Medical Emergency Policy and Procedure
- If harm has occurred and the Service User is unwell, call 999
- If the Service User does not appear immediately unwell, report the incident to the doctor responsible for the Service User's care
- During Out of Hours, call 111
- Report the incident immediately to the person in charge and record it
- Agree who will inform the Service User that a medication error has occurred
- Document the nature of the incident in the Service User's care records
- If the incident involves a dispensing error, inform the relevant pharmacy immediately

5.3 Action to be Taken by the Senior Member of Staff/Mr Damian Cummings Gillian Gilmore:

In the first instance:

- Check the medical status of the Service User if relevant, and check if any harm has occurred
- Ensure that all appropriate support has been offered to the member of staff involved in the incident
- Confirm that the Service User's GP has been informed and that the incident has been reported
- Ensure that the incident is recorded on the Service User's notes and an incident log made
- Once the Service User is stable, the Senior Member of Staff/Registered Manager must:
  - Ensure that a CQC notification is made (if there was harm to the Service User)
  - Ensure that St Helens is informed in line with local safeguarding procedures and in line with any contractual requirements (staff should refer to CR03 - Safeguarding Policy and Procedure and St Helens safeguarding policies and procedures)
  - Report incidents related to controlled drugs (including loss or theft) to the local NHS Controlled Drugs Accountable Officer
  - Where it applies, if there is an adverse drug reaction (and as discussed with the GP), complete the Yellow Card Scheme reporting process
  - Consider if Duty of Candour applies, and refer to ar38 - Duty of Candour Policy and Procedure to determine this
  - Investigate the incident using a Root Cause Analysis (RCA) to review what caused it
  - At the appropriate time, allow the member(s) of staff involved in the incident to reflect on the circumstances and identify their own learning

- Identify if there are any training or performance issues with the member(s) of staff, and depending on the level of risk, take any necessary actions which could involve immediately suspending a member of staff from dispensing, preparing or administering medication
- Reflect on ensuring that there remains an open, honest and transparent culture to raising concerns, and consider reinforcing key supportive policies to staff such as PM11 - Whistleblowing Policy and Procedure

5.4 Action After the Incident has Occurred - Staff

After a medication error or near miss has occurred and all necessary immediate actions have been taken, it is important that there should be an opportunity for the staff member to discuss the incident with Mr Damian Cummings Gillian Gilmore as soon as possible after the incident. The purpose of the discussion is to:

- Enable the member of staff to reflect on the circumstances
- Allow the member of staff to discuss how they feel and discuss any concerns they may have
- Identify if there are any training or performance issues with the member of staff
- Determine if the medication incident is a repeat incident (check if the member of staff has made a previous similar medication error and in what time frame)
- Dependent on the severity of the error/near miss, to ensure that all appropriate support has been offered to the member of staff

5.5 Being Open with Service Users Following a Medication Incident

It is important to be open and honest when things go wrong, therefore it is of great importance that a Service User is informed if a medication error has occurred.

- The Service User should be informed at an appropriate time and an apology offered
- If the error is of a serious nature, following the formal investigation and at the appropriate time, the Service User should be offered an opportunity to discuss the outcome of the investigation and to discuss its findings. This provides an opportunity to reassure the Service User that HWCGS Care (T/A Segal Gardens) is always eager to learn lessons from any medication errors, and to prevent similar occurrences in the future
- Consent should be obtained from the Service User before discussing any medication errors with their family. If the Service User is unable to consent due to the lack of mental capacity, the person responsible for their best interests should be informed
- Care should be taken not to cause unnecessary alarm to the Service User, and information should be provided in a way that is easy to understand and enables the Service User to ask questions
- If at any time the Service User or their representative is unsatisfied with the management of a medication incident, staff should signpost them to the complaints process as detailed within QQ03 - Complaints, Suggestions and Compliments Policy and Procedure

5.6 Root Cause Analysis (RCA)

- The RCA process starts by holding a meeting and stating the problem. The staff (can be one person but they should have the skills, knowledge to challenge, and seniority to question individuals) nominated to investigate the incident should gather documentation (MARs, Care Plans, Service User Notes, Incident Reports, etc.) and interview the staff involved in the error to find out the sequence of events. This is called the Fact Find Investigation and will result in a timeline of events
- The RCA team will review the documentation and sequence of events and continue asking themselves “Why did this happen?” until they arrive at each root cause
- The team must assume that any problem is preventable and caused by weak or vulnerable processes, rather than individual incompetence. Even in the case of a person making a mistake, the team must ask “Why do our systems allow these types of mistakes to happen so easily?” or “What factors set this person up to make this error?”
- Try to focus on the process rather than on an individual to encourage an open culture where staff are willing to report errors
- The Investigation should ask and get answers to the following questions:
  - What happened?

- What normally happens?
- What do the policies/procedures say about how it should be done?
- Why did it happen?
- How was HWCGS Care (T/A Segal Gardens) managing the risk before the event?

5.7 Actions from Root Cause Analysis

When the investigation has finished, the investigators should review the following to understand what went wrong and how to prevent the error occurring again. These 'lessons learnt' will be used as evidence of providing a safe service:

- How can we decrease the chance of the event occurring again?
- How can we decrease the degree of harm if the event were to occur again?
- What is best practice (when considering changing local procedures or rules)?
- How can devices, software, work processes or workspace be redesigned?
- How can we reduce reliance on memory and vigilance by improving processes in the workplace?
- Is the proposed action achievable within the limitations of resources at HWCGS Care (T/A Segal Gardens)? (E.g. if the error occurred because of something out of the control of HWCGS Care (T/A Segal Gardens), review the factors that are in the control of HWCGS Care (T/A Segal Gardens)

Once this has been conducted, the information should be shared in a way that maintains confidentiality but ensures that staff understand why an error occurred and how to prevent it arising again.

6. Definitions

6.1 Near Miss

- An error that is detected before the Service User is handed the medication

6.2 Root Cause Analysis (RCA)

- A process (sometimes described as a tool) to help identify what, how, and why an event occurred so that steps can be taken to prevent future occurrences

6.3 Medication Errors

- An incident where an error in the process for the prescribing, preparing, administering (including an omission), monitoring or the provision of medication advice, has occurred. This is regardless of whether any harm has occurred. Types of errors could be:
  - Omissions (any prescribed dose not given)
  - The wrong dose administered, e.g. too much or too little, extra dose given
  - Un-prescribed medicine (the administration of medication which has not been prescribed)
  - Wrong Service User
  - Wrong dose interval
  - Wrong administration route
  - Wrong time for administration
  - Not following ‘warning’ advice when administering, e.g. take with or after food
  - Administration of a drug to which the patient has a known allergy
  - Administration of a drug past its expiry date or which has been stored incorrectly
- HWCGS Care (T/A Segal Gardens) considers a medication error to be an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicine advice, regardless of whether any harm occurred

6.4 Timeline

- A useful tool when undertaking an investigation as it gives the time and date order of when things happened
- When the fact find is conducted it is important to ask staff for details of dates and times, to collate a timeline of events

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Key Facts - Professionals

Professionals providing this service should be aware of the following:

- All staff involved in the administration of medication have a responsibility to report errors, omissions, and near misses
- Each incident should be reviewed to understand what went wrong and to ensure that it does not happen again
- It is the responsibility of HWCGS Care (T/A Segal Gardens) to ensure that adequate systems for managing, administering and monitoring medication are in place, and a review of medication systems by an outside professional (e.g. a pharmacist) may help to identify any deficiencies
- HWCGS Care (T/A Segal Gardens) must notify the regulator of medication incidents where harm has been caused and follow local safeguarding procedures for reporting medication incidents. These records should be retained and accessible

Key Facts - People affected by the service

People affected by this service should be aware of the following:

- You should be informed if there is a medication error that affects you
- You should be made aware of how to raise a complaint and if you need support to make a complaint this should be arranged

Further Reading

As well as the information in the 'underpinning knowledge' section of the review sheet we recommend that you add to your understanding in this policy area by considering the following materials:

Institute for Safe Medicines Practice, Root Cause Analysis Workbook for Community/Ambulatory Pharmacy - (This is a US publication but is a useful document):
https://www.ismp.org/tools/rca/RCA-Complete.pdf

Staff can refer to the Suite of Medication Management Policies and Procedures, and the following HWCGS Care (T/A Segal Gardens) policies and procedures:

- Complaints, Suggestions and Compliments Policy and Procedure
- Safeguarding Policy and Procedure
- Duty of Candour Policy and Procedure
- Whistleblowing Policy and Procedure
- Distribution of Safety Alert Broadcasts, Rapid Response Reporting and Safety Notices Policy and Procedure

Outstanding Practice

To be ‘ outstanding ’ in this policy area you could provide evidence that:

- All errors and near misses with respect to medication are recorded and reported in a timely manner and according to legislation
- All errors and near misses are discussed at team meetings and followed up with robust written action plans to prevent a further recurrence. The learning is shared with staff responsible for medication errors
- There is a record of each error and the action taken
- There is a process in place for receiving and acting upon medication and safety alerts
- The wide understanding of the policy is enabled by proactive use of the QCS App

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Forms

The following forms are included as part of this policy:

Title of form	When would the form be used?	Created by
Medication Incident Report Form - CM15	To record medication near misses, discrepancies and errors.	QCS
Examples of Medication Errors - CM15	To guide staff on what a medication error is.	QCS
Medication Error Levels of Harm - CM15	To identify the level of harm following a medication error.	QCS

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Details of Service User Affected by the Medication Incident	
Name of Service User:	
Room Number:	
Date of Birth:	

Details of Medication Incident	
Date of Incident:	**Time of Incident:**
Names of Staff Involved:	
Name of Person Completing Report:	

Describe the Incident:

Why Do You Think It Happened?

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Did it involve a GP, District Nurse or Pharmacist? If so, how?
What actions (if any) were taken to minimise the impact on the Service User?
If harm occurred, describe any injuries:

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What actions have you taken to prevent the incident arising again?	
What do you think caused the incident, that if corrected, would stop the incident arising again?	
Date GP/Pharmacist/111 Informed?	
What was the Advice From GP/Pharmacist/111?	

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What Medication was involved in the incident?		
	What was correct?	**What was incorrect?**
Name of Medication:		
Dose:		
Route:		
Type of Medication (e.g. tablet, liquid, etc.):		

Name of Person Completing the Form:			
Date of Form Completion:			
Root Cause Analysis Completed? If so, Date:	**Yes**	**No**	**Not Applicable**
CQC Notified? If so, Date:	**Yes**	**No**	**Not Applicable**
Safeguarding Referral Required:	**Yes**	**No**	**Not Applicable**

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Prescribing

- Duplicate medicine
- A drug prescribed by both brand and generic names, e.g. Losec and Omeprazole
- Two medicines that have the same action, e.g. Omeprazole and lansoprazole
- Wrong dosage, strength or formulation
- Issuing of a discontinued medicine
- Medication requested from surgery but no prescription supplied without reason
- A Service User is prescribed a medicine that they are allergic to
- A Service User is prescribed a medicine that is contraindicated
- A Service User is prescribed a medicine that is unnecessary for them
- A Service User is prescribed a medicine that has an unwanted interaction with another medication that they are taking

Monitoring

- Monitoring not requested/requested but not done/results not available
- Results not acted upon
- Examples of drugs requiring monitoring include: Warfarin, Digoxin, Diuretics, Amiodarone, Thyroxine, Lithium, Insulin, Clozapine and some anti-rheumatic drugs

Dispensing

- Supply of duplicate medication
- Dose/strength/formulation error
- Wrong drug, no supply, deteriorated drug
- Labelling error

Administration

- Omission for any reason, including no stock
- The error involved someone being given another person's medication which is not prescribed for them
- Extra doses, wrong doses, allergy
- Wrong medicine, formulation error, deteriorated drug, timing error, wrong route

Ordering and Record Keeping

- Stock not ordered
- Stock not booked in correctly
- Stock not carried forward correctly
- Booking in of discontinued/not prescribed medication
- Stock not stored in the appropriate location
- Controlled Drug (CD) records not completed correctly
- Medication Administration Record (MAR) not signed
- MAR signed inappropriately, e.g. signed by another Support Worker

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Level of Harm	Definition	Example
No Harm	Any medication incident that did not result in harm or injury, that had the potential to cause harm, but was prevented resulting in no harm (Near Miss).	Penicillin was prescribed for a Service User with a Penicillin allergy. This was noticed by the Registered Nurse when she was checking the Medication orders.
Low Harm	Any medication incident that required extra observation or minor treatment.	A Service User was given a diuretic at the wrong time, that resulted in passing urine frequently late at night.
Moderate Harm	Moderate harm incidents are any medication incident that resulted in a moderate increase in treatment and which caused significant, but not permanent, harm.	A Service User is given someone else's medication. The medication is stronger than their own and they suffer drowsiness and their respiratory rate needs monitoring.
Severe Harm	Severe harm incidents are any incidents that appear to have resulted in permanent harm, including but not limited to death.	A Service User is given someone else's medication. They have an allergic reaction to it, have a cardiac arrest and suffer brain damage because of receiving the medication.
Death	Any unexpected or unintended event that caused the death of one or more persons.	A Service User is given someone else's medication. They have an allergic reaction to it, have a cardiac arrest and die because of receiving the medication.