



GUIDELINES FOR THE CONTROL AND ADMINISTRATION OF MEDICINES

DOMICILIARY CARE AGENCIES

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1.0 INTRODUCTION

These guidelines provide advice on the management of medicines by Domiciliary Care Agencies, with the aim of promoting the safe and effective use of medicines and ensuring that suitable and high quality care is provided to service users. They will help agencies and the workers they employ to achieve compliance with the regulations and standards for medicines management.

The guidelines cover the main aspects of the management of medicines, as detailed in the Domiciliary Care Agencies Minimum Standards (the minimum standards) and associated criteria, and include:

- details of the requirements and minimum standards for medicines for domiciliary care agencies
- levels of support to be provided to service users
- roles and responsibilities
- care plans
- policies and procedures
- training of staff and competency assessment
- record keeping
- storage of medicines
- errors, incidents and audit

This document has been written with reference to *The Domiciliary Care Agencies Regulations (Northern Ireland) 2007*, the minimum standards and guidelines issued by the Commission for Social Care Inspection (CSCI).

2.0 BACKGROUND

As a result of widespread support for a new system of regulation, covering a wider range of care services in Northern Ireland, *The Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003* (the Order) was developed.

The Order allows the DHSSPS to publish Regulations for establishments and agencies. The Order also allowed for the establishment of the Regulation and Quality Improvement Authority (RQIA), an independent body with responsibility for and powers to regulate establishments and agencies within the statutory and independent sectors.

Compliance with *The Domiciliary Care Agencies Regulations (Northern Ireland) 2007* is **mandatory**.

The DHSSPS has also produced minimum standards for a range of regulated services. The regulations and minimum standards for domiciliary care agencies detail the minimum provisions below which no provider is expected to operate. They focus on ensuring that people using the services are provided for and protected and care is quality assured.

Regulation 15(7) of *The Domiciliary Care Agencies Regulations (Northern Ireland) 2007* requires the registered person to:

“Make arrangements for the recording, handling, safe keeping, safe administration and disposal of medicines used in the course of provision of personal services to service users.”

Standard 7 of the Domiciliary Care Agencies Minimum Standards relates to the management of medicines and states that:

“The agency has arrangements in place to ensure that care workers manage medicines safely and securely.”

The 14 associated criteria statements listed under Standard 7 of the Domiciliary Care Agencies Minimum Standards cover the key areas of service provision for the management of medicines. This guidance document will advise agencies how compliance with the standard can be achieved. It will also highlight areas of good practice which will help agencies provide a quality service to service users in the community.

3.0 CRITERIA

In this section of the document, each criterion detailed in Standard 7 of the Minimum Standards for Domiciliary Care agencies will be highlighted and guidance on meeting the criteria will be given.

3. Referral

Criterion 7.1: *Where a service user has difficulty in managing his or her medicines, a mechanism is in place to ensure that there is a referral to the community pharmacist for medicines management scheme, and advising the health and social care (HSC) trust as appropriate.*

The placing agency (usually the Trust) should establish if a service user has difficulty in managing medication. The placing agency should, where possible, consult the local community pharmacist to determine what help is available through the Medicines Management Scheme.

3.2 Levels of assistance/consent

Criterion 7.2: *Administration of, or assistance with, medication is facilitated when requested by the referral agent, in situations where the service user is unable to self-administer and there is no other carer available, with the informed consent of the service user (or where the assessment indicates he or she is not able to give informed consent, his or her representative) and the agreement of the care worker's line manager, and not contrary to the agency's policy.*

Where the referral agent has identified that a service user is unable to take full responsibility for self-administration of medicines, the level of assistance to be provided by the domiciliary care agency should be identified. The level of assistance to be provided must be detailed in the service user's care plan. The care plan should clearly indicate if the care worker is to provide assistance with the administration of medication or if they are to administer medication to the service user. The care plan must also indicate if any medicines are to be administered by specialised techniques. The different levels of support that may be required are detailed in criterion 7.4.

Consent to administer medicines

Once the support needs for the management of medicines have been identified, the service user must agree to the care worker assisting with their medication or administering their medication in accordance with the care plan. This consent should be in writing and should be recorded in the care plan.

Where a service user is not able to give informed consent, the general medical practitioner who is responsible for treatment should be consulted and should be asked to indicate in writing that the treatment is in the best interest of the individual. The service user's relatives/advocates should be included in this process, but they are not authorised to give consent for treatment.

The wishes of service users who are able to consent to receive medication but refuse to do so must be respected, even if this could have an adverse effect upon their condition.

If a service user refuses to take their prescribed medication they must never be forced to take it against their will. The refusal must be recorded on the record sheet and the care worker must inform their line manager, who will inform the GP and the social worker as appropriate.

3.3 Multi-agency provision

Criterion 7.3: *Where packages of care may be provided on a multi-agency basis, policies and procedures on the management of medicines are agreed between the agencies and followed.*

As the responsibility for medicines management may be shared between a number of different agencies, agreement should be reached as to which agency has overall responsibility for the management of medicines. The agency with overall responsibility for medicines should be identified during the initial assessment of need and details should be indicated in the service user's care plan.

There should be policies and procedures in place for the review of arrangements, particularly if there are any changes to medication and/or level or type of support required. The agency with overall responsibility for medicines should have procedures in place for notifying the other agencies of any changes to medication or levels of support to be provided.

3.4 Care plans

Criterion 7.4: *The agency ensures that the administration of or assistance with medication is detailed in the care plan and forms part of the risk assessment*

As detailed in Standard 3.3, the care plan should include information on:

- the care and services to be provided to the service user
- directions for the use of any equipment
- the administration or assistance with medication
- how specific needs and preferences are to be met
- the management of identified tasks

The assessment of care needs may identify that the service user is unable to take full responsibility for the management of their medicines. This may be due to impaired cognitive awareness, e.g. as in dementia, and/or as a result of physical disability or impairment. The assessment of care needs will inform the level of assistance to be provided to service users.

Care workers may only administer medication or assist with medication in accordance with the details in the service user's care plan.

3.5 Levels of support

With respect to the administration of or assistance with medication, different levels of care provision have been identified. It is important to differentiate between providing assistance with medication and administering medication.

3.5.1 Level 1 Support – General support or assistance with medication

General support needs should be identified at the care assessment stage and recorded in the service user's care plan. Domiciliary care staff assisting with medication must receive suitable training and should only give assistance with medication under instruction from their manager and in accordance with the service user's care plan.

Level 1 support is given when the service user takes responsibility for their own medication, i.e. the service user indicates to the care worker what actions they are to take on each occasion.

The support given under Level 1 may include:

- requesting repeat prescriptions from the GP
- collecting medicines from the community pharmacy
- disposing of unwanted medicines safely by returning the supply to the community pharmacy (when requested to do so by the service user). Possible risks/potential dangers when disposing of medicines should be identified and the agency should ensure that there is a good audit trail and some element of management/supervision
- manipulation of a container, for example opening a bottle or popping tablets or capsules out of a blister pack at the request of the service user and when the care worker has not been required to select the medication

3.5.2 Level 2 Support – Administering medication

Administration of medication may include some or all of the following:

- selecting and preparing medicines for immediate administration (including medicines in monitored dosage cassettes and liquid medicines)
- applying creams and ointments
- inserting drops to ear, nose or eye
- assisting with the administration of inhaled medicines

If the agency accepts tasks relating to the administration of medication:

- the tasks must be within the care worker's competence
- the care worker must have received appropriate training for the tasks they are to perform and been deemed competent to carry out such tasks by an appropriate health care professional
- the service user must have given consent for the tasks to be carried out in their home
- the tasks must be within the terms and conditions of the agency's policy for the management of medicines

To ensure the safe administration of medicines by care workers the following details must be documented in the service user's care plan:

- the nature and extent of help required
- a current list of prescription medicines including:
 - name of medicine
 - dose
 - time of administration
 - frequency of administration
 - method of assistance
 - arrangements for the management of monitored dosage cassettes
 - arrangements for the management of any medicines to be administered on an "as required" basis, e.g. pain relieving medication

3.5.3 Level 3 Support – Administering medication by specific technique

See Criterion 7.9

3.6 Monitored dosage systems (MDS)

Medicines may sometimes be dispensed into monitored dosage cassettes. This must be done by a community pharmacist or a dispensing doctor and may be provided under the Medicines Management Scheme. The monitored dosage cassette must be prepared, sealed and labelled by a community pharmacist or dispensing doctor.

The arrangements for the provision and use of an MDS cassette must be agreed at the assessment of care needs stage and details of use should be recorded in the care plan.

Under no circumstances may a care worker place medicines into an unsealed compliance aid for service users to administer at a later time, nor may they administer medicines from an unsealed compliance aid which has been filled by a service user or their relative/advocate or any other health care professional. Medicines must only be administered from the labelled container into which they have been dispensed by a pharmacist or dispensing doctor.

Agencies and care workers should be aware that some medicines are not suitable for inclusion in MDS cassettes, including medicines prescribed on an "as required" basis, soluble tablets and tablets which are prone to absorbing

water or sensitive to light. The pharmacist or dispensing doctor dispensing the medicines is responsible for determining which medicines will be suitable for packaging into MDS cassettes.

When drafting policies and procedures and agreeing packages of care to be provided, agencies should be aware that it may not be possible to obtain medicines in an MDS system (as not all service users will be eligible to take part in the Medicines Management Scheme) and that some medicines cannot be dispensed in MDS cassettes.

3.7 Controlled drugs

As part of an agreed package of care, it may be necessary for care workers to be involved with the management of controlled drugs. Care workers should be made aware of the importance attached to the careful management of these drugs.

As a response to the recent Shipman enquiry into the misuse of controlled drugs, changes to the legislation for controlled drugs and policies and procedures for their management in a range of healthcare settings have been reviewed and updated.

Care workers should be made aware of the issues relating to controlled drugs as they relate to the domiciliary care setting. Where a care worker is required under the care plan agreement to collect supplies of controlled drugs for service users, they will be asked for proof of identification and proof that they have been authorised to collect controlled drugs on behalf of the service user before the pharmacist will issue supplies of controlled drugs to them.

Records of the receipt and return of controlled drugs to the pharmacist for disposal must be maintained. It is considered good practice for records of the return of controlled drugs to be signed by the pharmacist receiving them for destruction. Where possible, a second designated member of staff should witness the preparation and administration of a controlled drug and should sign the record of medicines administered.

Issues relating to storage of controlled drugs are addressed in criterion 7.12.

Agencies should be aware that care workers are particularly vulnerable when being asked to manage or assist with the management of controlled drugs in a domiciliary care setting.

3.8 Policies and procedures

Criterion 7.5: *The policy and procedures cover each of the activities concerned with the management of medicines.*

The operational policy for the agency must include reference to all arrangements for the management of medicines in the service user's home.

The RQIA Pharmacist Inspectors will look for evidence that the regulations and standards for medicines are being met through inspection of written policies and procedures which should include reference to the agency's arrangements for the following:

- roles and responsibilities (organisational/care workers)
- training and competency assessment
- seeking advice about medication issues
- service level agreements to manage medicines
- parameters and circumstances for care workers administering or assisting with medication
- record keeping
- accurate maintenance of personal medication records
- obtaining prescriptions
- disposal of medicines
- non-prescribed (over the counter (OTC)) medicines
- safe keeping of medication
- incident reporting

Where an agency does not provide a service, e.g. it does not collect or dispose of medicines, this should be clearly stated in the policy document.

Where agencies are responsible for provision of care in other regulated sectors, e.g. day care centres, residential care or nursing homes, the organisation must have a policy and procedure which relates specifically to the management of medicines in the domiciliary care setting.

3.9 Administration of medicines

Criterion 7.6: *The policy and procedures identify the parameters and circumstances for care workers administering or assisting with medication. They identify the limits and tasks that may not be undertaken without additional training.*

Agencies must ensure that the appropriate personal liability insurance is in place for all staff.

The agency's written policy and procedures must provide clear and comprehensive guidance to support the care worker which includes:

- when the care worker may assist with medication or administer medication
- the limitations of assistance with medication (prescribed and non-prescribed) and which tasks may not be undertaken without additional training
- detailed procedures for the safe handling of medication including:
 - requesting repeat prescriptions
 - collecting prescriptions and dispensed medication
 - procedure for administration, including the action to be taken should the service user refuse the medication
 - procedure for removal of unwanted medication
 - records of medication procurement
 - records of medicines administration
 - records of medicine disposal (return)
 - management of medication errors and incidents
- instructions regarding seeking guidance from a supervisor or line manager if any changes to the agreed parameters and circumstances for assisting with or administering medicines is proposed by the service user or their relative/advocate or any other individual, i.e. the policy should state that Agency staff must never attempt to provide care which is not identified in the service user's care plan and for which they are not trained or equipped.

The policy should be clearly stated and understood by all staff as well as referral agencies/purchasers, service users and their families and other health care professionals.

3.10 Training and competency assessment

Criterion 7.7: *Care workers who administer medicines are trained and competent. A record is kept of all medicines management training completed by care workers and retained for inspection.*

The registered manager of the domiciliary care agency is responsible for the developing and monitoring of the medication policy and for the provision of training to staff. Where the management of medicines is included in a service

user's care plan, the agency manager must ensure that care workers receive training on the safe handling of medicines.

The essential elements of this training should include:

- how to prepare the correct dose of medication
- how to administer different forms of medication, including tablets, capsules and liquid medicines given by mouth; ear, eye and nasal drops; inhalers; and external applications
- the responsibility of the care worker to ensure that medicines are only administered to the person for whom they were prescribed, giving the right (prescribed) dose, at the right time by the right method/route
- checking that the medication 'use by' date has not expired
- checking that the person has not already been given the medication by anyone else, including a relative or care worker from another agency
- recognising and reporting possible side effects
- reporting refusals and medication errors
- how a Care Worker should administer medicines prescribed on an 'as required' basis, for example, pain killers, laxatives
- what Care Workers should do when people request non-prescribed medicines
- understanding the service provider's policy for record keeping

The agency is responsible for obtaining evidence that the trainer is knowledgeable in the subject and has relevant current experience of handling medicines.

Agency staff should have access to a current copy of the British National Formulary (BNF).

Criterion 7.8: *The impact of medicines management training is evaluated as part of the quality improvement process and through supervision and appraisal of care workers.*

The agency must assess if the care worker is sufficiently competent in medication administration before being assigned the task. Records of training and competency assessments must be maintained and be available for inspection. Competency assessment and appraisal of care workers should be carried out on an annual basis.

3.11 Training in specific techniques

Criterion 7.9: *When necessary, training in specific techniques (e.g. the administration of eye/ear drops or the application of prescribed creams/lotions) is provided for named care workers by a qualified health care professional.*

Following an assessment by a health care professional, a domiciliary care worker may be asked to administer medication by a specific technique.

If the task is to be delegated to the domiciliary care worker, the health care professional must provide the necessary training and documented evidence that the care worker is competent.

Care workers can refuse to assist with the administration of medication by specific techniques if they do not feel competent to do so.

Domiciliary care agencies can refuse to provide services or tasks if they are not within the terms and conditions of the agency's policy for the management of medicines.

3.12 Record keeping

Criterion 7.10: *The agency ensures that the care worker documents, on each occasion, the administration of or assistance with medication.*

Where care workers are required to administer medicines to service users, the agency must ensure that a full and accurate personal medication record is maintained for each service user that includes:

- which medicines are prescribed
- when each medicine must be given
- what the dose is
- any special information, such as giving the medicines before food

The agency must have a clear procedure for amending the personal medication record when a service user's medication is altered.

All agency workers must keep a record of any medicines administered, including the dose administered and the date and time of administration. This record must be signed.

If a service user refuses to take their prescribed medication they must never be forced to take it against their will. The refusal must be recorded on the record sheet and the care worker must inform their line manager, who will inform the GP and the social worker as appropriate.

Criterion 7.11: *The agency ensures that, where care workers are involved, records are kept of all requests for, receipt and disposal of medicines.*

A suitable recording system should be in place that reflects the level of support provided by the agency.

3.13 Storage of medicines

Criterion 7.12: *The agency ensures that all those involved in the management of the service user's medication agree the arrangements for the safe storage of medication within the service user's home.*

The safe storage of medicines is the responsibility of the service user but as part of the service level agreement, care workers may be asked to ensure that medicines are stored safely and securely and in accordance with the manufacturers' instructions and to raise any concerns about storage with the appropriate healthcare professional. Where a service user is confused or otherwise thought likely to mistake their doses, a safe storage strategy must be agreed in co-operation with those involved in the care of the individual.

Care workers must report any signs of service users inadvertently taking additional doses or tampering with medication to the relevant health care professional. This action should be recorded. Extra care should be taken when controlled drugs are being stored in a service user's home and advice about storage of such medicines should be sought from the local community pharmacist.

3.14 Errors and incidents

Criterion 7.13: *Medication errors and incidents are reported, in accordance with procedures, to the appropriate authorities.*

Medication errors include medication being wrongly administered, omitted doses, duplicated doses, administration of discontinued medication and medication being lost or stolen.

Agencies should maintain an open "no blame" policy, where staff are encouraged to report medication errors without delay.

Errors by care workers must be reported immediately to their line manager who will notify the RQIA and all other relevant parties.

In all cases, the safety of the service user should be the primary concern and where necessary, the prescriber and/or emergency services should be contacted without delay.

The registered manager of the agency should investigate any errors or incidents to determine the root cause of the error, to identify areas of poor practice or non-compliance with policies and procedures for the management of medicines and to determine if there are any training or competency issues.

When reporting errors and incidents to the RQIA, the report should include full details of the incident and investigation, any factors which may have contributed to the error and the steps to be taken to reduce the likelihood of the incident reoccurring.

3.15 Audit

Criterion 7.14: *Practices for the management of medicines are systematically audited to ensure that they are consistent with the agency's policy and procedures and action is taken where necessary.*

The need for ongoing assessment and audit and identification of risks by the staff of the agency is necessary to ensure that the agency meets the needs of each service user and that the safety of the service user is assured.

Useful contacts

The Regulation and Quality Improvement Authority (RQIA)

9th Floor Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Tel. (028) 9051 7500
email: info@rqia.org.uk
Web www.rqia.org.uk

Lead Pharmacist Inspector: Mrs. Frances Gault

RQIA
'Hilltop'
Tyrone and Fermanagh Hospital
Omagh
BT79 0NS

Tel. (028) 8224 5828

Department of Health, Social Services and Public Safety

Castle Buildings,
Belfast
BT4 3SQ

Tel. (028) 9052 2028
Web www.health-ni.gov.uk

Commission for Social Care Inspection

Web www.csci.org.uk

Useful publications

The Domiciliary Care Agencies Regulations (Northern Ireland) 2007
http://www.opsi.gov.uk/sr/sr2007/nisr_20070235_en_1

The Domiciliary Care Agencies Minimum Standards
http://www.rqia.org.uk/cms_resources/Domiciliary%20Care%20Standards%20Jul%202008.pdf