



A consultation paper

Supplementary Guidance for Pharmacists in Northern Ireland on the Provision of Collection and Delivery Services

July 2010

1. BACKGROUND

This Supplementary Professional Guidance document is designed to assist pharmacists in delivering high quality and efficacious care to patients when operating collection and delivery services. It starts from the principle that, whilst it is important that patients have access to convenient pharmaceutical services, the best, and safest, pharmaceutical service is provided where the opportunity exists for direct contact between patients and a pharmacist, which would normally take place in a pharmacy.

It is based upon the existing Standards and Guidance framework of the Pharmaceutical Society of Northern Ireland (which is **not** subject to current consultation), draft guidance on Collection and Delivery services developed by the Health and Social Care Board (HSCB) in 2009, and the considerations of the Legislation, Standards and Practice Committee, and the Public Forum, of the Pharmaceutical Society of Northern Ireland. It is also in part drawn from guidance and best practise highlighted by other organisations, for example, the RPSGB's Guidance on Collection and Delivery Services from Central Points, and various Primary Care Trust and Board Guidance issued across the UK.

It is important to note that this guidance is **supplementary to (and does not replace)** the core Standards framework provided on this service issue within sections 6 and 7 of the Pharmaceutical Society of Northern Ireland's Professional Standards on the Sale and Supply of Medicines¹, published in July 2009.

2. SECTIONS 6 AND 7 OF THE PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND'S PROFESSIONAL STANDARDS ON THE SALE AND SUPPLY OF MEDICINES (JULY 2009)

The following have been MANDATORY Professional Standards for all pharmacists in Northern Ireland since July 2009 and are **not** the subject of current consultation:

DELIVERY SERVICES STANDARDS

A delivery service is where the medicine is handed to the patient or their carer other than on registered pharmacy premises. When providing medicines via a delivery service the pharmacist still has a professional responsibility to ensure that patients or their carers know how to use the medication safely, effectively and appropriately and to check that they are not experiencing adverse effects or compliance difficulties.

The pharmacist **must** ensure that:

¹ <http://www.psn.org.uk/documents/313/Standards+on+Sale+and+Supply+of+Medicines.pdf>

- 6.1. on each occasion a delivery service is provided he uses his professional judgement to determine whether direct face-to-face contact with the patient or their carer is necessary;
- 6.2. he obtains consent from the patient to provide the delivery service, confirms consent on each occasion, as appropriate, and maintains appropriate records of requests for the service;
- 6.3. the delivery mechanism used:
- enables the medicine to be delivered securely and promptly to the intended recipient with any necessary information to enable safe and effective use of his medicine;
 - provides for any special security/storage requirements of the medicine;
 - incorporates a verifiable audit trail for the medicine from the point at which it leaves the pharmacy to the point at which it is handed to the patient or their carer, or returned to the pharmacy in the event of a delivery failure;
 - safeguards confidential information about the medication that a patient is taking.

PRESCRIPTION COLLECTION SERVICE STANDARDS

A prescription collection service encompasses any scheme where a pharmacy receives prescriptions other than directly from the patient, their carer or their representative.

When providing such a service the pharmacist **must**:

- 7.1. obtain consent to collect/receive patients' prescriptions. The request for the ongoing service must be from the patient or their carer and procedures must exist for maintaining records of the initial request for the service;
- 7.2. explain fully to patients, or their carers, what the service involves, including the time period required to collect/receive and dispense their prescription;
- 7.3. ensure that any members of staff who collect prescriptions on his behalf are acting in accordance with his directions;
- 7.4. take all reasonable steps to ensure patient confidentiality and the security of prescriptions;
- 7.5. ensure he obtains consent from the patient or carer before requesting a repeat prescription from a surgery. The pharmacist may himself establish a patient reminder system;
- 7.6. on receipt of prescriptions, including electronic prescriptions, be satisfied that he is authorised to collect/receive and dispense them. Any prescription for which he does not

have the authority, must be returned to the surgery for collection by the patient or carer, or be directed to the pharmacy authorised to receive it;

7.7. where more than one pharmacy is involved in supplying prescriptions a SOP must be in place with detailed governance arrangements.

The next section of this document, expands on the existing Standards for Collection and Delivery by providing additional professional guidance to pharmacists in Northern Ireland on various aspects inherent in the provision of such services. It is structured around 3 core principles to be observed, and is the subject of current consultation.

KEY PRINCIPLES OF COLLECTION AND DELIVERY SERVICES

Three key principles to observe when offering Collection and Delivery services are:

1. The Responsible Pharmacist² overseeing the arrangements of a collection and delivery service, has professional accountability for the process and systems during the period of his involvement.³
2. The quality and safety of a pharmaceutical service is best assured where the opportunity exists for direct contact between patient and pharmacist at the point of supply, which would normally take place in a pharmacy.
3. A pharmacist must respect and protect confidential information and provide a high standard of practice and care at all times⁴

CONSULTATION QUESTIONS

- 1) Do you agree with the 3 key principles to be observed when offering collection and delivery services?
- 2) Is there anything you suggest should be added, amended or withdrawn from the Key Principles?

² The role and duties of the Responsible Pharmacist are set out in the Medicines Act 1968 (as amended by the Health Act 2006) and The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. The Responsible Pharmacist is legally responsible for the “safe and effective” operation of the pharmacy and its services.

³ Pharmacists should therefore make sure that their professional indemnity insurance covers involvement in collection and delivery schemes.

⁴ See the 8 Principles of the Pharmaceutical Society of Northern Ireland’s Code of Ethics:
<http://www.psni.org.uk/professionals/code-of-ethics.php>

GOOD PRACTICE GUIDANCE SUPPORTING THE PRINCIPLES

PRINCIPLE 1: THE RESPONSIBLE PHARMACIST OVERSEEING THE ARRANGEMENTS OF A COLLECTION AND DELIVERY SERVICE HAS PROFESSIONAL ACCOUNTABILITY FOR THE PROCESS AND SYSTEMS DURING THE PERIOD OF HIS INVOLVEMENT

Scope of Accountability

Accountability for process and systems, includes, but is not limited to, those for:

- the obtaining and recording of patient consent;
- the delivery of medicines;
- clinical risk assessment and governance; and,
- the appropriate storage and security of medicines.

Good Governance

Good governance of any service within a pharmacy can be assured through the operation of well written Standard Operating Procedures, understood and adhered to by all pharmacy staff, and are reviewed on a regular basis and after any adverse incident.

Any Collection and Delivery Service offered by a pharmacy should be reflected within the Standard Operating Procedures of that pharmacy, not least the legally required Pharmacy Procedures set out in the Responsible Pharmacist Regulations 2008⁵.

The paragraphs below give further guidance on how pharmacists can achieve good governance, and protect patient safety within a Collection and Delivery Service.

Obtaining and recording of patient consent for Collection of a Prescription⁶

The pharmacy should hold a record of those patients who have consented to have their prescriptions collected from their GP or Dental practice. This applies to both one-off occurrences, and recurrent collections. Consent can be given in either written form (e.g. a completed consent form), or orally (e.g. by telephone).

There should be agreement with the GP practice about the procedures when a prescription collection service is offered to patients. These should ensure that prescriptions are available in a rational and timely manner for dispensing, patient data is protected and consent recorded.

Good practice requires that a pharmacist should, by way of an audit trail, maintain a log book of those prescriptions collected from a practice with the consent of a patient, which should be maintained for at least 2 years.

It is suggested that patient consent for delivery is also retained by the pharmacy for two years after the last delivery is made.

⁵ http://www.opsi.gov.uk/si/si2008/uksi_20082789_en_1

⁶ See the Pharmaceutical Society of Northern Ireland's Standards and Guidance on patient confidentiality for further information: <http://www.psnl.org.uk/documents/317/Standards+on+Patient+Confidentiality.pdf>

A useful template of a patient consent form, which could be amended for purpose, is available from the DHSSPSNI website: http://www.dhsspsni.gov.uk/patient_consent_form.pdf

Pharmacists seeking access to patient medical records should also obtain consent in a recordable format.

Ordering Prescriptions on behalf of a patient

A pharmacist may order a prescription on behalf of a patient, and on a recurrent basis, provided that:

- patient consent has been clearly obtained and is recorded;
- principles of medicines management are observed, including the rational and economic use of medicines; and,
- robust procedures exist within the pharmacy governing this process. This should include which staff are authorised to conduct this service, and the protocols for patient consent and data protection.

Other Arrangements and Processes for the Collection of Prescriptions

When prescriptions are collected on behalf of patients, arrangements should be in place to ensure:

- the security and confidentiality of prescriptions in transit from the surgery⁷; and,
- the safety of staff transporting the prescriptions.

If a duplicate prescription is accidentally collected by the pharmacy it should be returned to the prescriber as soon as possible.

Arrangements and Processes for the Delivery of Medicines

Pharmacists should endeavour to ensure that:

- medicines are delivered directly to the patient, carer or nominee; and,
- where a delivery is to a person other than the patient/carer, the person has been specifically designated by the patient or carer.

It is also good practice that a signature is obtained to indicate safe receipt of the medicines and there is a verifiable audit trail of prescriptions collected and dispensed via the Collection and Delivery Service. It is suggested that a delivery driver's record book is retained for two years from the date of the last delivery.

The relevant Pharmacy SOP should specify the action to be taken when it is not possible to make a delivery.

All tasks delegated to members of staff, including delivery, should only occur where the staff members are competent and trained to undertake those tasks.

⁷ For example, prescriptions should never be left on view in a transit vehicle

All professional services and activities should also be covered by professional indemnity insurance arrangements.

Arrangements should be in place to ensure the safety of staff delivering a dispensed prescription.

Clinical Risk Assessment of Repeat Prescriptions within a Collection and Delivery Service

As stated, it is a mandatory professional standard that *“When offering a patient a collection and delivery service on an ongoing basis, as part of a repeat prescription, the pharmacist must take steps to ensure appropriate clinical risk assessment is conducted”*

This should include paying particular attention to medicines which have the potential for over-use or abuse (such as paracetamol/opioid combinations and those medicines which otherwise can present high risk to patients in overuse. Pharmacists should not assume that a prescription is clinically valid just because it has been repeated over an extended period, and should be cautious of upward trends in the quantity or dose prescribed.

Good practice is that a medicines management review is conducted with a patient at least once a year.

Compliance Aids and Monitored Dosage Systems in the context of Collection and Delivery

Pharmacists may dispense medicines in compliance aids and monitored dosage systems within a collection and delivery service so long as standard requirements are being met, such as:

- the labelling and leaflet requirements of “dispensed medicinal products”⁸

It may be difficult to comply with the legislation when using some systems where there may be inadequate space for the labels to be affixed. However, it should be borne in mind that not labelling a dispensed medicine, in accordance with the relevant legislation (e.g. the Medicines Act) can constitute a criminal offence.

- Appropriate accompanying advice

Advice should be given to the patient that if the contents of the compliance aid are spilled, or otherwise dislocated, the patient should not try to put the medication back into the compliance aid, but should return to the pharmacy. The patient should be advised that no other person must repack or tamper with the supply after dispensing from a pharmacy. In the context of collection and delivery services, the pharmacist might give this advice by way of a telephone call to the patient, or a written note of advice accompanying the delivered medicines.

Controlled Drugs and Collection and Delivery Services

There is provision within Misuse of Drugs legislation to cover occasions where a controlled drug may temporarily be in the possession of a third party (e.g. a delivery person or postal carrier) while it is being transferred from one authorised person to another person who is entitled to be in possession of the drug.

However, the Home Office has advised that this provision would not allow schedule 2, 3 and schedule 4 Part 1 controlled drugs to be held at, and collected from, a central collection point. Additionally, safe custody and record keeping requirements could not be complied with.

⁸ See Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994

Therefore schedule 2, 3 and schedule 4 Part 1 Controlled Drugs must either be collected from the pharmacy by the patient or their representative, or delivered directly from the pharmacy to the patient's home.

It is good practice to keep any Controlled Drugs out of view during transit.

For any delivery, whether a controlled drug or not, the pharmacist retains overall responsibility for ensuring the item reached the intended patient.

Storage and security arrangements of medicines within a collection and delivery service

Pharmacists should be mindful of items that require additional storage and/or security arrangements for example:

- those requiring cool storage;
- those with a short shelf-life;
- items liable for misuse or abuse; and,
- Controlled Drugs.

Because of the nature of these products, they should not be included with a delivery service where an alternative method of supply is available.

Checks with patients at the point of delivery

At the point of supply it can be helpful to check with the patient or carer as to the number of prescription items the patient expected within the delivery. Any deviation from the expected number of items can then be clarified for patient benefit.

CONSULTATION QUESTIONS

- 3) Do you agree with the guidance supporting key principle 1 to be observed when offering collection and delivery services?
- 4) Do you agree with recommended periods of time for retaining records of delivery and consent?
- 5) Is there anything else you suggest should be added, amended or withdrawn in this section of the guidance?

PRINCIPLE 2: THE QUALITY AND SAFETY OF A PHARMACEUTICAL SERVICE IS BEST ASSURED WHERE THE OPPORTUNITY EXISTS FOR DIRECT CONTACT BETWEEN PATIENT AND PHARMACIST AT THE POINT OF SUPPLY, WHICH WOULD NORMALLY TAKE PLACE IN A PHARMACY

Contact with patients for the purposes of medicines advice

Where the pharmacist determines in his professional judgement that contact with the patient is required for the purposes of disseminating appropriate medicines advice, but face-to-face contact is impractical or not possible, efforts should be made to disseminate the advice by other means, such as a phone call to the patient, carer or patient representative, or a written advice note to accompany the delivery or collection.

Collection and Delivery from Central Points

Article 2 of the Medicines (Collection and Delivery Arrangements) Order 1978, which came into operation on 30 October 1978, states that restrictions imposed by Section 52 and 53 of the Medicines Act 1968 shall not apply to the supply of any medicinal product for human use on premises which are not a registered pharmacy, where such a supply is in accordance with a prescription given by a doctor or dentist, and forms part of a collection and delivery arrangement used by a person who lawfully conducts a retail pharmacy business.

Essentially this enables pharmacists to make arrangements for patients to drop off prescriptions issued by a doctor or dentist and collect the dispensed medicines from a general point that is not a pharmacy.

Whilst it remains preferable for medicines within a Collection and Delivery scheme to be delivered directly to a patient's home, it is recognised that this may not always be practical (e.g. in respect of small island populations).

Where dispensed medicines are to be collected from a central point, the pharmacist should take adequate measures to ensure security and the responsible handing out of medicines, and preferably ensure an audit trail for the receipt of the medicines which involves the recording of signed safe receipt of the medicines by the patient/carer/nominee.

Collection and Delivery from central points should be seen to be the exception rather than the normal route of supply. It is the consideration of the Pharmaceutical Society of Northern Ireland that any delivery process which distances the patient from the pharmacist, reduces personal contact, and limits the opportunities for expert intervention and advice about medicines use, has the potential to increase risk to a patient.

CONSULTATION QUESTIONS

- 6) Do you agree with the guidance supporting key principle 2 to be observed when offering collection and delivery services?
- 7) Do you think pharmacists should be able order prescriptions on behalf of patients?
- 8) Should pharmacies be able to use central collection points as a route of delivery?
- 9) Is there anything else you suggest should be added, amended or withdrawn in this section of the guidance?

PRINCIPLE 3: A PHARMACIST MUST RESPECT AND PROTECT CONFIDENTIAL INFORMATION AND PROVIDE A HIGH STANDARD OF PRACTICE AND CARE AT ALL TIMES

The protection of patient confidentiality⁹

Robust procedures should be in place to ensure the security of prescription forms, since any loss will have significant consequences in terms of data protection legislation as well as financial implications.

In the delivery of medicines, measures should be taken to abide by the principles of the Data Protection Act in respect of any sensitive information relating to the patient. This might include advising delivery drivers of the importance of respecting the privacy of a patient's medical history, or ensuring sensitive medical information is not easily discernible from external packaging.

In fulfilling patient confidentiality and data protection, retention and destruction requirements, Pharmacists may wish to refer to some of the Standard Operating Procedures developed by the National Pharmacy Association in 2009 including "*Delivery Medicines Safely and Effectively*¹⁰", "*The Roles and Responsibilities of Pharmacy Staff*¹¹" and "*Record Keeping*¹²".

Advertising and Customer reward schemes in relation to Collection and Delivery services

When considering the relationship between a collection and delivery service and any customer loyalty scheme that may be in operation within a pharmacy, the pharmacist must be mindful that medicines are not ordinary items of commerce and there is a professional responsibility to ensure that any customer loyalty scheme gives due regard to the special nature of medicines and does not encourage inappropriate or excessive consumption.

See the Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance on Advertising Medicines and Professional Services for more information and advice in this area:

<http://www.psn.org.uk/documents/315/Standards+on+Advertising+Services.pdf>

Handling complaints in relation to Collection and Delivery Services

Pharmacists are reminded of their legal obligation under the Responsible Pharmacist Regulations (2008) to maintain and update procedures for the handling of complaints. Good practice is that the members of staff employed within a pharmacy are made familiar with the complaints procedure, and the procedure that should be used to learn from any adverse, or near-adverse, incidents that occur within the pharmacy. Remedial actions should be made in a timely fashion.

⁹ See the Pharmaceutical Society of Northern Ireland's Standards and Guidance on patient confidentiality for further information: <http://www.psn.org.uk/documents/317/Standards+on+Patient+Confidentiality.pdf>

¹⁰ <http://www.npa.co.uk/Resources/SOPs/Delivering-medicines-safely-and-effectively/?type=site>

¹¹ <http://www.npa.co.uk/Resources/SOPs/Roles-and-responsibilities-of-pharmacy-staff/?type=site>

¹² <http://www.npa.co.uk/Resources/SOPs/Record-keeping/?type=site>

The National Pharmacy Association has produced a useful template SOP which details a complaints procedure that satisfies both the requirements of the responsible pharmacist regulations but also the applicable NHS legislation in the individual home countries.

<http://www.npa.co.uk/Resources/SOPs/Dealing-with-complaints/>

CONSULTATION QUESTIONS

10) Do you agree with the guidance supporting key principle 3 to be observed when offering collection and delivery services?

11) Is there anything else you suggest should be added, amended or withdrawn in this section of the guidance?

12) Are you aware of any potential equality impacts in relation to the Standards and Guidance framework for pharmacists in Northern Ireland on Collection and Delivery Services which should be given further consideration by the Pharmaceutical Society of Northern Ireland?

13) Do you have any other comments or suggestions in relation to this document and the Standards and Guidance framework for pharmacists in Northern Ireland on Collection and Delivery Services?

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