



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

FEBRUARY 2011

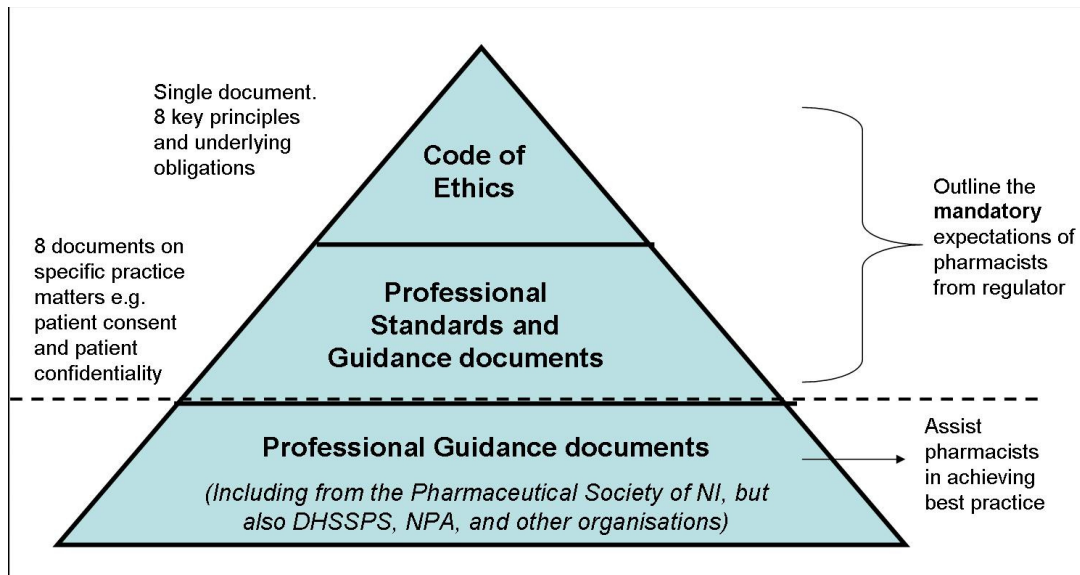
1. BACKGROUND

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

This guidance is supplementary to the existing Standards and Guidance framework of the Pharmaceutical Society of Northern Ireland, in particular those parts pertaining to prescription collection and delivery services in the Pharmaceutical Society of Northern Ireland's *Professional Standards on the Sale and Supply of Medicines*¹, published in July 2009.

The diagram below is a visual illustration of how this guidance document is placed within the Standards and Guidance Framework.

More information on the Standards and Guidance framework for pharmacists in Northern Ireland is available here: <http://www.psn.org.uk/professionals/code-of-ethics.php>



This Supplementary Guidance has been developed from:

- the considerations of the Health and Social Care Board (HSCB) in 2009 of the need for additional guidance relating to prescription collection and/or delivery services;

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

- Fitness to Practise case histories relating to prescription collection and/or delivery services;
- Learning outcomes from adverse, or near-miss potential adverse, incidents related to prescription collection and/or delivery services;
- the considerations of the Pharmaceutical Society of Northern Ireland's Legislation, Standards and Practice Committee;
- views and comments received from the Public Forum of the Pharmaceutical Society of Northern Ireland; and,
- Responses made to the public consultation on Draft Prescription Collection and/or Delivery Services Guidance held over the summer of 2010.

Reference has also been made to guidance and best practise highlighted by other organisations, for example, the RPSGB's Guidance on collection and/or delivery services from central points², and various Primary Care Trust and Board Guidance issued across the UK.

2. PATIENT SAFETY ISSUES THAT CAN OCCUR IN THE CONTEXT OF PRESCRIPTION COLLECTION AND/OR DELIVERY SERVICES

Pharmacists should be aware that serious patient safety issues can occur in the context of a prescription collection and/or delivery service, without appropriate governance and processes. These risks include, but are not limited to:

- the delivery of incorrect medicines to a patient;
- non-delivery of medicines due to errors in the delivery service;
- inadvertent breach of a patient's confidentiality; and.
- patient safety incidents with medicines as a result of reduced clinical governance and oversight by the pharmacist.

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

It is important to note that this guidance is **supplementary to (and does not replace)** the core Standards framework provided in relation to prescription collection and/or delivery services issued within sections 6 and 7 of the Pharmaceutical Society of Northern Ireland's Professional Standards on the Sale and Supply of Medicines³, published in July 2009, which is reproduced below for ease of reference. In offering and providing any prescription collection and/or delivery service, pharmacists should also pay due regard to other elements of the Standards and Guidance Framework, such as *the Professional Standards and Guidance for Patient Consent*⁴, and *the Professional Standards and Guidance for Patient Confidentiality*⁵.

² http://faculty.ksu.edu.sa/hisham/Documents/Files_For_MS_Students/13.pdf

³ <http://www.psni.org.uk/documents/313/Standards+on+Sale+and+Supply+of+Medicines.pdf>

⁴ <http://www.psni.org.uk/documents/318/Standards+on+Patient+Consent.pdf>

⁵ <http://www.psni.org.uk/documents/317/Standards+on+Patient+Confidentiality.pdf>

The following have been MANDATORY Professional Standards for all pharmacists in Northern Ireland since July 2009:

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:

- 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 prescription collection and/or delivery by providing supplementary professional guidance to pharmacists in Northern Ireland on various additional aspects inherent in the provision of such services. It is structured around 2 core principles that pharmacists should have regard to in offering and administering a prescription collection and/or delivery services.

KEY PRINCIPLES WITHIN PRESCRIPTION COLLECTION AND/OR DELIVERY SERVICES

Key principles for pharmacists to have particular regard to when operating any prescription collection and/or delivery service are:

1. The Responsible Pharmacist⁶ overseeing the arrangements of a prescription collection and/or delivery service has local professional accountability for the process and systems during the period of his/her involvement⁷ at the pharmacy in question.⁸ The superintendent pharmacist has responsibility for company systems and processes operated in a body corporate.
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.

⁶ 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 Pharmaceutical Society of Northern Ireland has published and issued Standards and Guidance supporting the Regulations, which are available at: <http://www.psnl.org.uk/professionals/code-of-ethics.php>

⁷ Within an individual registered pharmacy premises, the Responsible Pharmacist has local accountability for implementation of Procedures and ensuring the safe and effective running of the pharmacy.

GOOD PRACTICE GUIDANCE SUPPORTING THE PRINCIPLES

PRINCIPLE 1: THE RESPONSIBLE PHARMACIST OVERSEEING THE ARRANGEMENTS OF A PRESCRIPTION COLLECTION AND/OR DELIVERY SERVICE HAS LOCAL PROFESSIONAL ACCOUNTABILITY FOR THE PROCESS AND SYSTEMS DURING THE PERIOD OF HIS/HER INVOLVEMENT AT THE PHARMACY IN QUESTION. THE SUPERINTENDENT PHARMACIST HAS RESPONSIBILITY FOR COMPANY SYSTEMS AND PROCESSES OPERATED IN A BODY CORPORATE

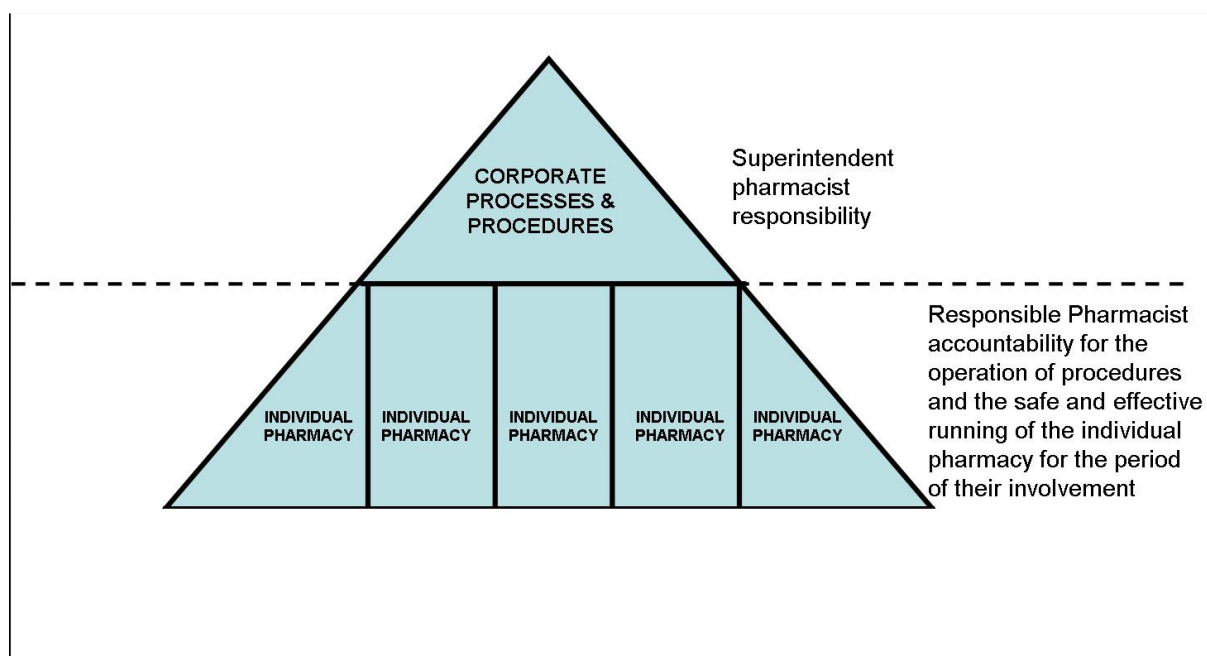
1.1 Scope of Accountability

The Responsible Pharmacist's accountability for process and systems in a registered pharmacy premises, includes, but is not limited to, those for:

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

The superintendent pharmacist has responsibility for company systems and processes operated in a body corporate.

The diagram below gives a visual illustration of the respective scope of accountability of the Responsible Pharmacist and Superintendent.



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 which are reviewed on a regular basis and after any adverse incident. Any changes made should

⁸ Pharmacists should therefore make sure that their professional indemnity insurance covers involvement in

be noted and document control systems used to highlight which SOP is (and was) operating at any given point in time.

Any prescription collection and/or delivery service offered by a pharmacy should be reflected within the Standard Operating Procedures of that pharmacy, not least the legally required Pharmacy Procedures as set out in the Responsible Pharmacist Regulations 2008⁹.

The paragraphs below give further guidance on how pharmacists can achieve good governance, and protect patient safety within a prescription collection and/or delivery service.

1.2 Obtaining and recording patient consent for Collection of a Prescription¹⁰

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. Although consent can be given verbally (e.g. by telephone) and recorded, best practice is to obtain consent from the patient in a written form.

A useful template of a patient consent form, which can be amended for purpose, is available from the Pharmaceutical Society of Northern Ireland's website¹¹. Use of this template is not mandatory. It is good practice to record the patient's contact telephone number with their consent in case of any event, query or delay in relation to their prescription.

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

Pharmacists seeking access to patient medical records from the GP or Dental practice should also obtain consent from the patient in a recordable format.

1.3 Prescription Collection and/or Delivery Service Audit Trails

Good practice is that a pharmacist should, by way of an audit trail, maintain a record of those prescriptions collected from a practice with the consent of a patient as well as the prescriptions delivered. This record could be maintained within existing patient medication record systems (PMR), or through any separate process.

In keeping with the NPA Standard Operating Procedures on Record Keeping¹², the Pharmaceutical Society of Northern Ireland recommends that pharmacists retain records of

collection and delivery schemes.

⁹ http://www.opsi.gov.uk/si/si2008/uksi_20082789_en_1

¹⁰ 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>

¹¹ <http://www.psn.org.uk/documents/765/Template+Collection+and+Delivery+Patient+Consent+Form.doc>

¹² http://www.chemistanddruggist.co.uk/c/document_library/get_file?folderId=2496516&name=DLFE-16514.doc

patient consent for prescription collection and/or delivery, and the delivery driver's record book, for a period of 2 years from the date of last delivery/collection.

1.4 Arrangements and Processes for the Collection and/or Delivery of Medicines

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 surgery¹³;

If a duplicate prescription is issued by the surgery it should be returned to the prescriber as soon as possible.

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.

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.

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 prescription collection and/or delivery service.

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.

All professional services and activities should also be covered by professional indemnity insurance arrangements¹⁴.

1.5 Storage and security arrangements of medicines within a prescription collection and/or 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 within a prescription delivery service where an alternative method of supply is available.

¹³ For example, prescriptions should never be left on view in a transit vehicle

¹⁴ See Code of Ethics, 8.11 “Ensure that all professional activities undertaken by you, or under your control, are covered by appropriate professional indemnity arrangements.”

1.6 Controlled Drugs and Prescription Collection and/or Delivery Services

Whilst noting the above guidance, that Controlled Drugs should not be included within a prescription delivery service where an alternative method of supply is available, it is recognised that in some situations an alternative method may not be available.

Accordingly, 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 advise 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 (see also guidance on Collection, Delivery and Supply of Medicines from Central Points in next section). Additionally, safe custody and record keeping requirements could not be complied with. 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. A signature of receipt should be recorded and maintained for the delivery of Controlled Drugs.

For any delivery, whether a Controlled Drug or not, the Responsible Pharmacist of the individual pharmacy retains overall responsibility for ensuring the item reaches the intended patient.

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

2.1 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 directly to the patient, carer or patient representative, or a written advice note to accompany the delivery or collection.

2.2 Collection, Delivery and Supply of Medicines 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/dentist and collect the dispensed medicines from a general point that is not a pharmacy.

Whilst it remains preferable for medicines within a prescription collection and/or 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, isolated rural areas or experience of severe weather conditions e.g. isolation due to road flooding or heavy snow). Collection and/or delivery from central points should be considered by pharmacists to be an exceptional, rather than a normal, route of medicines supply.

Pharmacists are reminded that it is not suitable to allow Controlled Drugs to be collected from central collection points, as provisions within Misuse of Drugs legislation only 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.

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.

PRESCRIPTION COLLECTION AND/OR DELIVERY SERVICES IN THE CONTEXT OF HOSPITAL PHARMACY

This Guidance document has been developed primarily in view of safety risks presented by the operation of prescription collection and/or delivery services offered to the public by community pharmacies. However, it is recognised that many patients in Northern Ireland also receive medications by way of delivery services provided by pharmacies in the secondary care sector (e.g. Red/Amber medicines, emergency on-call scenarios, dialysis fluids, ADHD stimulants etc).

Such services will be provided under the clinical governance arrangements of the relevant Trust/s in question. This guidance is not intended to replace those arrangements. However, professional advice to hospital pharmacists involved in prescription medicine delivery services direct to patients in the community is to ensure that any systems for delivery will:

- have identified and addressed any potential risks to patient safety (e.g. the risk associated with the medicines being delivered including to anyone who is not the patient);
- include mechanisms for compiling an audit trail for the sending and receipt of the medicines (e.g. use of recorded delivery); and,
- meet the requirements of professional accountability, as per the spirit of the Responsible Pharmacist Regulations.

Community pharmacists involved in facilitating the delivery of packages containing medicines dispensed by a hospital pharmacy by acting as a collection point, should take due diligence in ensuring appropriate steps to assure that the medicines are stored securely and appropriately for onward transit to a patient or their carer. Where appropriate the pharmacist should consider the necessity to maintain a record of the receipt and onward supply of any such packages (e.g. those which may contain Controlled Drugs).