

# **Community Pharmacy Assurance Framework Guidance Document**

**April 2017**

## 1. Introduction

A strategic goal of the Department of Health strategy document “Making it Better through Pharmacy in the Community”<sup>1</sup> is to ensure that throughout life, in accordance with their clinical needs, people have access to timely, safe, quality assured medicines supplied with appropriate advice and support to help them gain the best outcomes from their treatment and avoid harm.

The Health and Social Care Board (HSCB) commissions Pharmaceutical Services for the population of Northern Ireland and services are currently provided by 533 community pharmacy contractors. The Pharmaceutical Services (NI) Regulations 1997 specify Terms of Service for elements of pharmaceutical service provision and further services are defined within elective contract arrangements and individual service specifications.

In order to provide an assurance that patients and members of the public receive safe, effective and high quality pharmaceutical services, HSCB in collaboration with CPNI has developed a Community Pharmacy Assurance Framework (CPAF). The output from the assurance process will be a report of compliance with the requirements in the framework highlighting areas of good practice and areas of concern or for improvement. This guidance document details the steps in the process.

## 2. Aims of the Assurance Framework

The aim and purpose of the framework is to monitor compliance with Terms of Service, Service Specifications, related Professional Standards and Best Practice Guidance to ensure that patients and members of the public receive safe, effective and high quality pharmaceutical services.

## 3. Overview of the Framework

The CPAF consists of two components:

- (i) an annual declaration by each community pharmacy contractor, and
- (ii) a programme of visits, undertaken by HSCB staff, to each pharmacy over a three year period.

A summary flowchart describing the process is included as Appendix 1. Full details of the Framework and the relevant documentation can also be accessed on the Pharmaceutical Section of the BSO website at: <http://www.hscbusiness.hscni.net/services/2693.htm>

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<sup>1</sup> <https://www.health-ni.gov.uk/publications/making-it-better-through-pharmacy-community>

#### **4. Assurance Declaration Form**

The Assurance Declaration Form, (Appendix 2), will be issued annually by HSCB to all community pharmacy contractors. Contractors will have a number of weeks to return the declaration form to their local HSCB office. Any contractors who have failed to return the declaration by the due date will receive one follow up phone-call from staff in the local HSCB office.

The declaration will include dispensing and other core service indicators, Terms of Service indicators including the requirements for additional professional services and premises indicators reflecting the requirements for specific elective services e.g. MUR.

#### **5. Selection of pharmacies for assurance visits**

Each quarter approximately 9 pharmacies, per LCG area, will be selected for an assurance visit by HSCB staff. The basis of selection of pharmacies for visits will be:

1. Contractors for which no level of assurance is available to the HSCB i.e. the pharmacy has failed to submit the self-declaration proforma.
2. Contractors where further assurance is sought as a result of one of the following:
  - Reported adverse incidents and serious adverse incidents
  - Reported complaints from service users, and,
  - Concerns raised by whistle blowers or other healthcare professionals
  - Information reports from HSCB including prescription data, payment and monitoring information for elective services
3. Random selection

The selection process will normally be a mix of the above with priority being given to category 1 above.

#### **6. Purpose of visits**

The purpose of the visit will be to:

- observe evidence of the requirements of the assurance framework in practice;
- seek to view records and documentation as appropriate whilst respecting patient confidentiality; and

discuss, with the pharmacist and relevant pharmacy staff any aspects of service provision that are directly relevant to the service requirements. These will particularly apply where the requirements are related to premises or staff activity that cannot be easily assured by documentation alone.

## 7. Notification of the visits

HSCB staff will contact contractors when they have been selected for an assurance visit to arrange a suitable date and time. This will be followed up with a confirmation letter.

A copy of the visit protocol (Appendix 3) will be sent along with a copy of the pharmacy's completed assurance declaration form.

## 8. Preparation for a visit

The visit protocol (Appendix 3) provides detail of the topics and questions that will be covered during the visit. Contractors can review this in preparation for the visit and ensure supporting documentation is readily available for discussion during the visit.

## 9. Access to patients' records

During the visit the contractor may be required to provide evidence that patient medication records are being maintained to support certain aspects of the assurance process. There is a legislative basis for HSCB to inspect that records are being maintained for health service business. For the purpose of the assurance framework, the contractor will not need to provide names or other patient identifiable data to HSCB staff and there will be no necessity to remove any patient level data from the pharmacy.

## 10. The visit

The assurance visit will be conducted by a HSCB pharmacist accompanied by a HSCB practice support manager.

The contractor should ensure that the regular responsible pharmacist (pharmacist) is available for the duration of the visit. The contractor or another representative can participate if desired. The visit should last no longer than 1 hour during which time the HSCB pharmacist will discuss the questions on the visit protocol with the pharmacist. This will include a review of how processes work practically in the pharmacy and evidence or documents/records to support this may be requested. It may be necessary for the HSCB Adviser to take photographs e.g. of the consultation area, but permission will be asked of the pharmacist first.

Any follow-up actions will be discussed by the HSCB Adviser, the pharmacist and contractor (if in attendance) and agreed where possible. A record of actions will be made on the visit protocol. In exceptional circumstances additional information may need to be sought by the HSCB Adviser, post visit. These will be recorded as **Post Visit Comments** and **Actions** on the visit report.

Following the visit, a draft report will be sent to the contractor for review and comment as detailed in section 11 below.

## **11. Visit Report and Action Plan**

A draft report will be issued 2-4 weeks following the visit highlighting areas of good practice and areas of concern or for improvement. The report will be shared with the pharmacy for comment to ensure that the final report is accurate and agreed between the HSCB and pharmacy contractor.

The contractor will have 2-4 weeks to review and comment on the actions. Where the contractor has reported concerns, the HSCB pharmacist will work with the contractor to resolve concerns and agree actions. Once agreed, the final visit report will be issued along with an action plan, where appropriate. A copy of the action plan is included in Appendix 4.

## **12. Compliance with the Framework**

The emphasis of the assurance framework is to obtain assurance that pharmaceutical services are being delivered in accordance with relevant Service Specifications, Terms of Service, Professional Standards and Best Practice Guidance. When all actions identified in the visit have been completed or where there are none to complete, a letter of compliance with the requirements of the framework will be issued.

## **13. Addressing areas of concern**

Areas of under-performance will be addressed in the first instance through HSCB pharmacist engagement with the pharmacy to provide advice on the development of an action plan for improvement and offering support to implement this plan, including sharing of good practice.

In cases where there is a dispute between the contractor and the HSCB over an issue of compliance, e.g.

- The contractor does not accept that there is an issue of non-compliance
- The contractor and HSCB are unable to agree an action plan
- The HSCB does not agree that a problem has been sufficiently remedied,

Then the issue should be escalated within the relevant organisations or through an agreed independent third party in order to reach a resolution.

Arrangements such as buddying or mentoring to support individual pharmacies could be facilitated by the Board; however these would be private arrangements between the relevant parties.

The overall outcomes from the assurance process will inform the HSCB processes for commissioning and performance management. In the unlikely event that the assurance process identifies serious concerns about non-compliance, these will be dealt with under the HSCB procedures for addressing poor performance for independent contractors via

referral to the HSCB Regional Professional Panel (RPP) and/or the Pharmaceutical Society Northern Ireland. The remit and constitution of business for RPP is included in Appendix 5.

## 12. Funding Arrangements

In order to ensure the safe and effective delivery of pharmacy services during the visit funding will be available to cover locum costs for the day of the visit. This will enable the regular pharmacist to be available for the entirety of the visit and to allow sufficient time to make supporting documents / records available for discussion during the visit. Payment of £150 will be made upon receipt of a claim form, signed by, or on behalf of, the contractor on the day of the visit. Payment will only be made if the regular pharmacist has been freed up for the duration of the visit. A copy of the claim form is included in Appendix 6

## 13. Review of the Framework

The framework will be reviewed annually to ensure it still fulfils its purpose. Experience from implementation of the framework and topics of current interest will inform the review process.

## 14. Contact Details for further Advice

### Health and Social Care Board

If you wish to discuss any aspect of the framework with a HSCB pharmacist please contact your local Integrated Care Office and ask to speak to a pharmacy adviser. The details of the pharmacy co-ordinators in each local office are detailed below.

Belfast	Matthew Dolan Tel: 028 9536 3926 Email: <a href="mailto:Matthew.Dolan@hscni.net">Matthew.Dolan@hscni.net</a>
North	Fiona McConnell Tel: 028 9536 2592 Email: <a href="mailto:Fiona.McConnell@hscni.net">Fiona.McConnell@hscni.net</a>
South East	Helen Creighton Tel: 028 9536 1461 Email: <a href="mailto:Helen.Creighton@hscni.net">Helen.Creighton@hscni.net</a>
South	Teresa McAllister Tel: 028 9536 2037 Email: <a href="mailto:Teresa.McAllister@hscni.net">Teresa.McAllister@hscni.net</a>
West	Gillian Plant Tel: 028 9536 1084 <a href="mailto:Gillian.Plant@hscni.net">Gillian.Plant@hscni.net</a>

## **Community Pharmacy NI**

If you require any clarification, advice or support from CPNI, please contact

Kerry Grimes

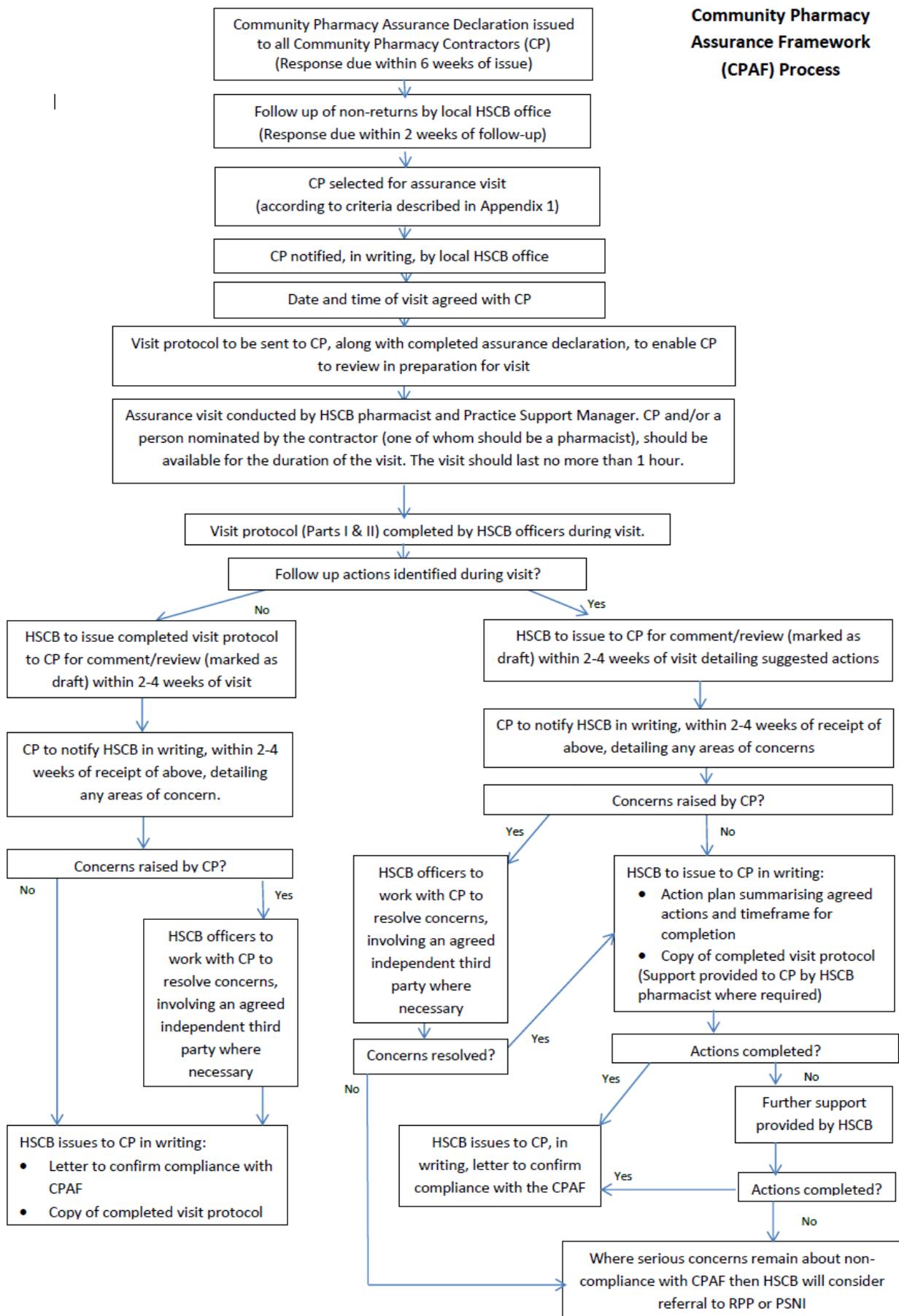
Governance Pharmacist

CPNI

Tel: 028 9069 0444

Email: [kgrimes@communitypharmacyni.co.uk](mailto:kgrimes@communitypharmacyni.co.uk)

# Appendix 1 CPAF Flowchart



### Community Pharmacy Assurance Declaration

April 2017 – March 2018

<b>Contractor Name &amp; Address:</b> (As per current Pharmaceutical List)	< completed by HSCB>	
<b>Trading Name</b> (If different from Pharmaceutical List)	Completed by Contractor	
<b>Contractor Number:</b>	< completed by HSCB>	
<b>HSCB Contact Details</b>	Address:	< completed by HSCB>
	Tel No.	< completed by HSCB>
	Fax No.	< completed by HSCB>
	Pharmacy Adviser:	< completed by HSCB>
	Email address:	< completed by HSCB>
	Practice Support Manager:	< completed by HSCB>
	Email address:	< completed by HSCB>

		Confirmed by Contractor
<b>Email address:</b>	< completed by HSCB>	<b>Yes/No</b> If <b>No</b> , please provide preferred email address for the Pharmacy:
	Do you consent to HSCB using this email address for regular correspondence?	<b>Yes/No</b>

## 1. Hours of Provision of Pharmaceutical Services

The Pharmacy's "Contracted Hours" are those detailed in the Pharmaceutical List:

<http://www.hscbusiness.hscni.net/services/2053.htm>

Community Pharmacies must open during **all** of their agreed contracted hours. Any requests to change contracted hours should be submitted in writing to BSO detailing the proposed changes and the reason for the changes.

<b>Contracted Hours</b>	(as per current Pharmaceutical list):  < completed by HSCB >	<b>YES</b>
		<b>NO</b>
		<b>Change has been requested with BSO</b>
<b>Opening Hours (Commercial)</b>	Please state your current opening hours:  <i>Valid on date of submission – opening hours beyond the contracted hours is at the discretion of the contractor.</i>	

## 2. Additional Professional Services - Practice Leaflet

Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997**

<http://www.hscbusiness.hscni.net/services/2539.htm> the Pharmacy Contractor is required to produce a Practice Leaflet which should include:

1. A list of the pharmaceutical services which the chemist has undertaken to provide and for which his name is included in the pharmaceutical list;
2. The name, address and telephone number of the premises from which he provides those services and the hours in each day of the week during which he provides those services from those premises;
3. The arrangements made by the chemist to provide, or such arrangements as the chemist has made with any other chemist to provide, pharmaceutical services to any person who needs those services in an emergency or outside of the normal hours during which the chemist provides pharmaceutical services (For example, display of rota key, rota information on BSO website or in local press, details of NI direct website <http://www.nidirect.gov.uk>, contact details of local GP OOH centres); and
4. The procedure by which any person may comment upon the provision of pharmaceutical services provided by the chemist.

<b>Practice Leaflet</b>	The pharmacy has a current practice leaflet which meets the requirements detailed above.	<b>YES</b>
		<b>NO</b>
		<b>Changes being actioned as a result of CPAF visit</b>
		<b>Please include a copy of the practice leaflet with this proforma ONLY if it is different to the one submitted for 2016/17</b>

### 3. Additional Professional Services – Health Promotion Leaflets

<b>Health Promotion Leaflets</b>	The pharmacy displays up to 8 health promotion leaflets	<b>YES</b>
		<b>NO</b>

### 4. Additional Professional Services – Record Keeping

Pharmaceutical Services Regulations (NI) 1997 Terms of Service requires pharmacists claiming Additional Professional Services payments to

2(c) keep records in connection with drugs supplied to any person -

- (i) who is aged 60 or over; or
- (ii) who, in the opinion of the chemist providing the drug, is likely to have difficulty understanding the nature and dosage of the drug provided and the times at which it is to be taken, in circumstances where the nature of the drug is such that, in the opinion of the chemist providing it, the same or a similar drug is likely to be prescribed for that person regularly on future occasions.

HSCB Dispensing Service Specification 3.2 requires that the pharmacy maintains a record of all medicines and appliance supplied to facilitate continued care of the patient.

<b>Record of medicines and appliances supplied to patients.</b>	The pharmacy maintains records of all HSC prescriptions dispensed.	<b>YES</b>
		<b>NO</b>

### 5. Complaints Procedure

Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997**

<http://www.hscbusiness.hscni.net/services/2539.htm> , every Pharmacy is required to have in place a complaints procedure which includes:

- Provision of information within the pharmacy about the complaints procedure
- A specified person who deals with complaints
- Management of complaints - all complaints must be;
  - Recorded in writing
  - Acknowledged within 3 working days
  - Properly investigated *and*
  - A written summary of the investigation and conclusions provided to the complainant within 10 working days.
- Keeping records of all complaints and associated correspondence

<b>Complaints Procedure</b>	The pharmacy has a current complaints procedure.	<b>YES</b>
		<b>NO</b>
		<b>Changes being actioned as a result of CPAF visit</b>
		<b>Please include a copy of the complaints procedure with this proforma* ONLY if it has changed from the one submitted for 2016/17</b>

\* A copy of the pharmacy's SOP for managing complaints may be submitted as the pharmacy's complaints procedure.

## 6. MUR Service – Consultation Area

The MUR service specification specifies that the part of the pharmacy used for the provision of MURs must meet the following requirements for consultation areas:

- the consultation area should be where both the patient and the pharmacist can sit down together
- the patient and pharmacist should be able to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)
- the consultation area should be clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy.

MUR service specification available at:

<http://www.hscbusiness.hscni.net/services/2427.htm>

<b>MUR Consultation Area</b>	MURs are provided in a consultation area which meets the requirements detailed above.	<b>YES</b>
		<b>NO</b>
		<b>N/A The pharmacy does not have a contract to provide the MUR service</b>

## 7. Dispensing

The requirements for dispensing by community pharmacy contractors are detailed in the Service Specification for Dispensing<sup>i</sup> and Pharmaceutical Services (NI) Regulations 1997 Terms of Service for Chemists<sup>ii</sup> and Professional Standards<sup>iii</sup>

<b>Dispensing</b>	Dispensing of HSC prescriptions is carried out in line with the Service Specification, Terms of Service and Pharmaceutical Society of NI professional standards to ensure that patients receive ordered medicines and appliances safely and to ensure that patients are able to use medicines and appliances effectively.	<b>YES</b>
		<b>NO</b>
<b>Dispensing SOPs</b>	There are SOPs in place to cover dispensing processes.	<b>YES</b>
		<b>NO</b>

**Signed by the Contractor/Superintendent or duly authorised signatory:**

.....

**Name (PRINT)**.....

**Position (please tick):**

Contractor  Superintendent  Pharmacy Manager  Pharmacist

Other  (please specify) .....

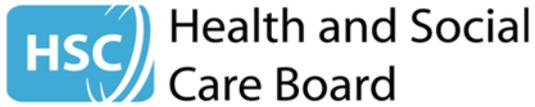
**Date:**.....

**PLEASE RETURN TO <insert local office details> BY Friday 19<sup>th</sup> May 2017**

**PLEASE ENCLOSE COPIES OF:** Practice leaflet   
*(if required)* Complaints procedure

### References

- i. Dispensing Service Specification
  - a. <http://www.hscbusiness.hscni.net/services/2652.htm>
- ii. Pharmaceutical Services Regulations (NI) 1997  
<http://www.hscbusiness.hscni.net/services/2539.htm>
- iii. Pharmaceutical Society of NI Standards
  - a. <http://www.psni.org.uk/about/code-of-ethics-and-standards/>



**Community Pharmacy Assurance Visit Protocol 17/18  
Part I - Terms of Service & Service Specification Requirements**

Contractor Number:	< completed by HSCB >	Confirm	Comments	Actions
<b>Contractor Name &amp; Address:</b>	(as per current Pharmaceutical list): < completed by HSCB >	<input type="checkbox"/> Yes <input type="checkbox"/> No		

**Q1. Hours of provision of pharmaceutical services**

**Context**

The pharmacy’s “Contracted Hours” are those detailed in the Pharmaceutical List: <http://www.hscbusiness.hscni.net/services/2053.htm>  
 Community pharmacies must open during **all** of their agreed contracted hours. Any requests to change contracted hours should be submitted in writing to BSO detailing the proposed changes and the reason for the changes.

		Confirm hours	Comments	Actions
<b>Contracted Hours</b>	(as per current Pharmaceutical list): < completed by HSCB >	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Opening Hours (Commercial)</b>	< completed by HSCB from declaration >	<input type="checkbox"/> Yes <input type="checkbox"/> No		

## Q2. Additional professional services - Practice leaflet

### Context

Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997** <http://www.hscbusiness.hscni.net/services/2539.htm> the pharmacy contractor is required to produce a practice leaflet which should include:

5. A list of the pharmaceutical services which the chemist has undertaken to provide and for which his name is included in the pharmaceutical list;
6. The name, address and telephone number of the premises from which he provides those services and the hours in each day of the week during which he provides those services from those premises;
7. The arrangements made by the chemist to provide, or such arrangements as the chemist has made with any other chemist to provide, pharmaceutical services to any person who needs those services in an emergency or outside of the normal hours during which the chemist provides pharmaceutical services (For example, display of rota key, rota information on BSO website or in local press, details of NI direct website <http://www.nidirect.gov.uk/choosewell>, contact details of local GP OOH centres); and
8. The procedure by which any person may comment upon the provision of pharmaceutical services provided by the chemist.

Question		Comments	Actions
Was the pharmacy's practice leaflet submitted with the annual assurance declaration?  < completed by HSCB >	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Does the leaflet include? <ul style="list-style-type: none"> <li>• Name, address &amp; telephone number.</li> <li>• List of pharmaceutical services</li> <li>• Opening hours</li> <li>• Out-of-hours arrangements</li> <li>• Complaints/comments information</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Is the practice leaflet on display in an easily accessible part of the pharmacy?	<input type="checkbox"/> Yes <input type="checkbox"/> No		

## Guidance Notes

Template leaflets produced for use by community pharmacy in other regions of the UK may contain references which are not relevant to Northern Ireland e.g. NHS, Primary Care Trusts, Health Authorities. Please ensure the terminology used in your leaflet is appropriate for Northern Ireland.

To comply with Terms of Service, the Pharmaceutical Services listed should only be those provided in the premises named on the leaflet. Terms of Service states, "A list of the pharmaceutical services which the chemist has undertaken to provide and for which his name is included in the pharmaceutical list". It is not acceptable to have one leaflet to cover services provided across a group of pharmacies which are not provided in the individual named pharmacy. Provision of oxygen is a pharmaceutical service which should be included in the leaflet if listed in the pharmaceutical list.

### Q3. Additional professional services – Health Promotion Leaflets

#### Context

Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997** <http://www.hscbusiness.hscni.net/services/2539.htm> the pharmacy contractor is required to display health promotion leaflets.

Question		Comments	Actions
Are there up to 8 health promotion leaflets on display?	<input type="checkbox"/> Yes <input type="checkbox"/> No		

#### Q4: Additional Professional Services - Record keeping

##### Context

Pharmaceutical Services Regulations (NI) 1997 Terms of Service requires pharmacists claiming Additional Professional Services payments to 2(c) keep records in connection with drugs supplied to any person -

(iii) who is aged 60 or over; or

(iv) who, in the opinion of the chemist providing the drug, is likely to have difficulty understanding the nature and dosage of the drug provided and the times at which it is to be taken, in circumstances where the nature of the drug is such that, in the opinion of the chemist providing it, the same or a similar drug is likely to be prescribed for that person regularly on future occasions.

HSCB Dispensing Service Specification 3.2 requires that the pharmacy maintains a record of all medicines and appliance supplied to facilitate continued care of the patient.

Pharmaceutical Society of NI's The Code, Standard 2.3 requires pharmacists to record, store and process data clearly and accurately. Standard 2.3.4 requires all records to be kept securely and in an organised manner and for the appropriate period of time.

Question	Confirmation/ additional information	Comments	Actions
What is the process used for keeping records of all HSC prescriptions dispensed?			

##### Guidance Notes

During the visit a series of questions may be asked and requests may be made to see records that are required to be kept, where these may be disclosed without breaching confidentiality.

Department of Health's Good Management, Good Records Section M, outlines the requirements for retention and disposal of community pharmacy held records: <https://www.health-ni.gov.uk/articles/disposal-schedule-section-m>

## Q5. Complaints procedure

### Context

Under **Terms of Service, Pharmaceutical Service Regulations (NI) 1997** <http://www.hscbusiness.hscni.net/services/2539.htm> , every pharmacy is required to have in place a complaints procedure which includes:

- Provision of information within the pharmacy about the complaints procedure
- A specified person who deals with complaints
- Management of complaints - all complaints must be:
  - Recorded in writing
  - Acknowledged within 3 working days
  - Properly investigated *and*
  - A written summary of the investigation and conclusions provided to the complainant within 10 working days.
- Keeping records of all complaints and associated correspondence

Question		Comments	Actions
Was the pharmacy's complaints procedure submitted with the annual assurance declaration? < completed by HSCB >	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Is there a specified complaints contact? (name or job title)	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Does the procedure include the required steps for the management of complaints? <ul style="list-style-type: none"> <li>• Recorded in writing</li> <li>• Acknowledged within 3 working days</li> <li>• Properly investigated <i>and</i></li> <li>• A written summary of the investigation and conclusions</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No		

<p>provided to the complainant within 10 working days.</p> <ul style="list-style-type: none"> <li>Keeping records of all complaints and associated correspondence</li> </ul>			
<p>Are complaints dealt with within the required timescales detailed in Terms of Service?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<p>Is there information within the pharmacy about the complaints procedure? e.g. HSCB template leaflet or poster</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		

### Guidance Notes

Resources to help support the management of complaints are available on the BSO website <http://www.hscbusiness.hscni.net/services/2659.htm>

These include:

- a HSCB template poster and leaflet on complaints procedures
- a link to e-learning on the management of complaints

## Q6. MUR service – consultation area requirements

### Context

The MUR service specification (<http://www.hscbusiness.hscni.net/services/2427.htm>) specifies that the part of the pharmacy used for the provision of MURs must meet the following requirements for consultation areas:

- the consultation area should be where both the patient and the pharmacist can sit down together
- the patient and pharmacist should be able to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)
- the consultation area should be clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy

### Current MUR Activity

Pharmacy contracted to provide the MUR service                      Yes / No

No of Initial Reviews:            Latest Quarter <insert dates> <number inserted by HSCB>    Year to date <number inserted by HSCB>

Question		Comments	Actions
Can both the patient and the pharmacist sit down together?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Is it possible to talk at normal speaking volumes without being overheard by any other person (including pharmacy staff)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Is the consultation area clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy?	<input type="checkbox"/> Yes <input type="checkbox"/> No		

# Community Pharmacy Assurance Visit Protocol - Part II

## Core Essential Service - Dispensing

### Service description

The supply of medicines and appliances<sup>2</sup> ordered on HSC prescriptions, together with information and advice, to enable safe and effective use by patients and carers, and maintenance of appropriate records.

### Aims and intended outcomes

To ensure patients receive ordered medicines and appliances safely and appropriately by:

- the pharmacy performing appropriate legal, professional, clinical and accuracy checks
- the pharmacy having safe systems of operation
- the pharmacy having systems in place, in line with The Code, to guarantee the integrity of products supplied
- the pharmacy maintaining a record of all medicines and appliances supplied which can be used to assist future patient care
- the pharmacy maintaining a record of advice given, and interventions and referrals made, where the pharmacist judges it to be clinically appropriate

To ensure patients are able to use their medicines and appliances effectively by:

- pharmacy staff providing information and advice to the patient or carer on the safe use of their medicine or appliance
- pharmacy staff providing when appropriate broader advice to the patient on the medicine, for example its possible side effects and significant interactions with other substances

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<sup>1</sup> Pharmacies are required to supply any drugs ordered via a prescription. With regards appliances they are only required to supply those that they supply in the normal course of their business.

## Q1: Dispensing SOPs

### Context

The Responsible Pharmacist Regulations 2008 requires the responsible pharmacist to establish pharmacy procedures designed to ensure the safe and effective running of the pharmacy. These procedures need to be maintained and regularly reviewed:

- 2.5 Pharmacy Procedures are regularly reviewed to ensure they are fit for purpose and reflect the day to day running of the specific pharmacy premises and any changes are documented accordingly
- 2.6 Review of the Pharmacy Procedures occurs every two years as a minimum or at any time that an incident occurs which may potentially have led to a compromise of patient safety

Question	Confirmation/ additional information	Comments	Actions
What SOPs are in place to cover dispensing processes? (an in-depth review will not be undertaken)	If template/company SOPs are used can they be adapted for local use in the pharmacy?		
Are they signed by all relevant staff to say they have read it, understand it, and will follow it, or staff have demonstrated competency and have been signed off by pharmacist?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Are the SOPs easily accessible by relevant staff? (hard or electronic format)	<input type="checkbox"/> Yes <input type="checkbox"/> No		

Have the SOPs been reviewed within the last two years?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
What is the process for review?			

## Q2: Clinical assessment of prescriptions

### Context

Pharmaceutical Society of NI Professional Standards & Guidance for the Sale and Supply of Medicines 3.2 &3.4 and HSCB Dispensing Service Specification 2.1, state that a clinical assessment of every prescription is undertaken, by a pharmacist, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient and appropriate records of clinical interventions are made.

Question	Confirmation/ additional information	Comments	Actions
Can you describe the process for undertaking a clinical assessment of a prescription?	Does the process include steps for: <ul style="list-style-type: none"> <li>• determining the suitability of medication,</li> <li>• appropriateness of the quantity and</li> <li>• dose frequency for the patient?</li> </ul>		
Does the pharmacist address clinical queries directly with the prescriber?	<input type="checkbox"/> Yes where possible <input type="checkbox"/> No  Do you have any difficulties speaking directly to the prescriber?		
Are interventions and referrals recorded in a log book or PMR?	<input type="checkbox"/> Yes <input type="checkbox"/> No  Ask to see an anonymised example. e.g. Is there a record of: <ul style="list-style-type: none"> <li>• the date and time</li> <li>• patient details</li> <li>• a summary of the</li> </ul>		

	query and outcome <ul style="list-style-type: none"> <li>the name of the pharmacist and GP/healthcare professional involved?</li> </ul>		
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## Guidance Notes

### Clinical Check

Advice on clinical assessment is available in the HSCB Medicines Safety Matters newsletter

<http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-community-pharmacists/>

In summary the clinical check consists of reviewing:

- **The patient** - characteristics e.g. children or elderly, co-morbidities, patient preferences, allergies
- **The medicines** - indication, dose, frequency, strength, quantity & prescribing interval, interactions, route of administration

Pharmacy Forum has produced Clinical check Guidance which is available at <http://forum.psni.org.uk/whats-happening/guidance/>

### Clinical Queries

Every effort should be made to speak directly to the prescriber if there is a clinical query. This is particularly important where there are serious concerns about patient safety e.g. relating to abuse/misuse, serious drug interactions or overdose. A number of adverse incidents have been reported to HSCB where queries were not discussed between healthcare professionals and guidance on community pharmacy communication with GPs was issued in May 2013 and again in July 2015.

<http://www.medicinesgovernance.hscni.net/primary-care/medicines-safety-advice-letters/>

### Recording Interventions

Records of interventions can be recorded on the PMR or in a designated book. Ideally including:

- the date and time
- a summary of the query and outcome
- patient details
- the name of the pharmacist and GP/healthcare professional involved

### Q3: Accuracy of dispensing

#### Context

Pharmaceutical Society of NI Professional Standards for the Sale and Supply of Medicines:

3 states that patients are entitled to expect the dispensing service provided to be accurate

3.14 requires procedures to be in place to minimise the risk of dispensing errors

Question	Confirmation/ additional information	Comments	Actions
Can you describe the process for undertaking an accuracy check of a prescription			
Is there is a double check built into your dispensing process where possible?	<input type="checkbox"/> Yes <input type="checkbox"/> No		

#### Guidance Notes

The Royal Pharmaceutical Society of Great Britain suggests the mnemonic HELP maybe be useful when carrying out the final accuracy check on a dispensed medicine:

H – How much has been dispensed

E – Expiry date check

L – Label checks for the correct patient's name, drug name, dose and warnings

P – Product check, i.e. correct medicine, strength and formulation have been supplied

For all prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS, ensure that there is a double check built into your dispensing process where possible. This may be another pharmacist or member of dispensary staff and should be included in your SOP.

#### Q4: Provision of PILs

##### Context

Pharmaceutical Society of NI Professional Standards and Guidance for the Sale and Supply of Medicines 3.15 states that a patient information leaflet (PIL) is issued with a medicine at the time of dispensing.

Question	Confirmation/ additional information	Comments	Actions
Do you routinely issue a patient information leaflet (PIL) with each full and part pack of medicine at the time of dispensing?  Can you describe the process?	<input type="checkbox"/> Yes <input type="checkbox"/> No  What is the process for getting extra supplies of PILs and ensuring they are the most up-to-date editions?  Discuss arrangements for supplying PILs with MDS.		

##### Guidance Notes

Extra copies of leaflets should be available for supply with split packs or stock pots. These could be provided by the manufacturer or by downloading a leaflet.

EMC website: <https://www.medicines.org.uk/emc/>

MHRA website: <http://www.mhra.gov.uk/spc-pil/>

Advice on the supply of PILs is given by the Medicines Regulatory Inspectors in their newsletter Issue 3, November 2007 and in respect of MDS in Issue 6, December 2010. <https://www.health-ni.gov.uk/publications/pharmacy-inspector-newsletters-june-2006-june-2015>

## 5: Labelling

### Context

Pharmaceutical Society of NI, Professional Standards and Guidance for the Sale and Supply of Medicines 3.11, states that labelling of dispensed products is clear and legible, computer-generated and where appropriate includes any cautionary and advisory labelling recommended by the BNF.

Question	Confirmation/ additional information	Comments	Agreed Actions
Do you ensure a label is supplied with each pack/container*?	<input type="checkbox"/> Yes <input type="checkbox"/> No  Does MDS packaging contain a label for every item supplied in the compliance aid?		

### Guidance Notes

Medicines Regulatory Group Inspectors Newsletter No 10 March 2015 includes a message from the Pharmaceutical Society of NI Registrar on managing labelling risks. "Good professional practice requires each and every product should be supplied with its own discrete label to aid patients and carers in ensuring the safe and correct usage of the product ". <https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/pas-pharmacy-newsletter-10.pdf>

\* Possible exceptions to this may be the supply of dietetic products or surgical products where outer packaging could be labelled once. Consider labelling for all types of prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS.

## Q6: Provision of advice to patients

### Context

Pharmaceutical Society of NI Professional Standards and Guidance for the Sale and Supply of Medicines:

- 3.3 requires that the patient receives sufficient information and advice to enable the safe and effective use of the prescribed medicine and
- 6.3 that the pharmacist must ensure that 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

HSCB Dispensing Service Specification 3.3 requires that appropriate advice is given to the patient to enable them to utilise the medication or appliance and to meet their personal need for general information on the item.

Question	Confirmation/ additional information	Comments	Actions
<p>Do you ensure that appropriate advice is given to patients (or their representatives) on their prescribed medicines including home deliveries, for</p> <ul style="list-style-type: none"> <li>• New medicines</li> <li>• Changes to medicine dose or formulation</li> <li>• High risk medicines</li> </ul>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>What steps are taken to ensure that advice is given when a prescription is handed out in the pharmacy e.g. use of alert labels etc.?</p> <p>What steps are taken to ensure that advice is given when a prescription is delivered?</p>		

### Guidance Notes

HSCB High Risk Medicines Poster (CP version) is available at: <http://www.medicinesgovernance.hscni.net/primary-care/posters-leaflets/>

## Q7: Safe storage of medicines

### Context

HSCB Dispensing Service Specification 3.4 requires that patients are advised on the safe storage and keeping of medicines and of the recommendation that unwanted medicines should be returned to the pharmacy for safe destruction.

Pharmaceutical Society of NI Standards for Sale and Supply of Medicines 3.10: The pharmacist must ensure that all solid dose and all oral and external liquid preparations are dispensed in suitable re-closable child resistant containers unless:

- The medicine is in an original pack or patient pack such as to make this inadvisable;
- The patient has difficulty in opening a child resistant container;
- A specific request is made by the patient, their carer or representative that the product is not dispensed in a child resistant container;
- No suitable child resistant container exists for a particular liquid preparation; or
- The patient has been assessed as requiring a compliance aid.

Pharmaceutical Society of NI Standards for Sale and Supply of Medicines 1.7: The pharmacist must ensure that the removal of medicines from blister or foil packs only, where required, at the time of dispensing, is to assist an individual patient. In doing so, the integrity of the medicine must not be impaired.

Question	Confirmation/ additional information	Comments	Actions
How do you ensure patients are advised on the safe storage and keeping of medicines?	Discuss the process e.g. practice leaflet		
How do you raise awareness with patients that unwanted medicines should be returned to the pharmacy for safe destruction?	e.g. DUMP campaign, practice leaflet		

How do you check the suitability of medicines that are supplied in MDS?	e.g. UKMI Medicines Compliance Aid Database		
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### Guidance Notes

Consider advice on safe storage e.g. for fridge lines and methadone, and other medicines with special advice for disposal e.g. eye drops requiring disposal after 28 days, safe disposal of patches.

Consider advice on the disposal of unwanted medicines either verbally or written as appropriate e.g. note on dispensing bag or posters/leaflets.

Medicines Safety Matters Community Pharmacy Vol 3 Issue 2 (July 2015) focused on incidents involving Monitored Dosage Systems, how to reduce the associated risks and advice on drug stability.

Information on the stability of medicines prior to dispensing in MDS can be accessed on the Specialist Pharmacist Service Website <https://www.sps.nhs.uk/?s=&cat%5B%5D=266&cat%5B%5D=3253>. Enter the drug name in the search bar, click on the specific medicine that is retrieved on the list that is displayed, and scroll down the page to the advice on MCA stability for that specific medicine.

## Q8: Checking patient details

### Context

Pharmaceutical Society of NI Standards and Guidance for the Sale and Supply of Medicines 3.14, requires that procedures are in place to minimise the risk of dispensing errors.

Question	Confirmation/ additional information	Comments	Actions
<p>Can you describe the process for confirming patient details, before handing out medicines, to ensure the right patient gets the right prescription</p> <ul style="list-style-type: none"><li>• In your pharmacy?</li><li>• When medicines are delivered?</li></ul>	<p>Are you aware of the “Right Person” poster?</p>		

### Guidance Notes

E.g. Pharmacy staff say the patient’s name and ask the patient/carer for the address.

Consider all types of prescriptions e.g. acute, repeat, instalment, for care homes or those supplied in MDS.

HSCB “Right Person” poster is available at: <http://www.medicinesgovernance.hscni.net/primary-care/posters-leaflets/>

## Q9: Patient Safety

### Context

Pharmaceutical Society of NI Code for Professional Standards of Conduct, Ethics and Performance, Principle 2 requires pharmacists to provide a safe and quality service with Standard 2.2. focusing on Managing Risk. These require pharmacists to:

- 2.2.1, Undertake a regular risk assessment in relation to your professional practice and the procedures that you follow
- 2.2.2, Apprise staff of medication safety issues, identify areas of high-risk practice and implement procedures and processes to minimise medication safety risks or associated issues arising
- 2.2.3, Where any risk, issue or problem is identified, arises, or occurs in your practice, take prompt action to prevent, minimise, follow up and resolve any such risk, issue or problem, and this includes risks, issues or problems relating to medicines and appliances.
- 2.2.4, Keep abreast of medication safety alerts and other publications to ensure the safety and quality of pharmacy services
- 2.2.5, Contribute appropriately to “near-miss” and error reporting systems.

Pharmaceutical Society of NI Professional Standards for the Sale and Supply of Medicines 3.14 requires procedures to be in place to minimise the risk of dispensing errors or contamination of medicines and a record of errors and near-miss incidents must be made and practices reviewed in light of such incidents.

Question	Confirmation/ additional information	Comments	Actions
What is the process for disseminating patient safety communications e.g. HSC Learning Letters, Medicines Safety Matters Newsletters and other relevant communications from the HSCB to dispensing staff?*			
How do you record medicines incidents and near-misses?	Ask to see an anonymised example of an incident or near miss record.		

How do you review practice with relevant staff in light of any incidents e.g. in the pharmacy or one highlighted in a patient safety communication?			
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**Guidance Notes**

\* Medicines safety advice, letters and newsletters are available on the NI Medicines Governance Website

<http://www.medicinesgovernance.hscni.net/primary-care/>

**Q10a Topic of current interest – Beta blockers**

**Additional Context**

Communications have been issued by HSCB to share learning from a number of adverse incidents where beta blockers were involved in selection errors at the point of dispensing, some of which had serious consequences for the patients involved. Confirmation was required from pharmacies that the actions from the Beta blocker learning letter issued in May 2014 were completed.

Question	Confirmation/ additional information	Comments	Actions
HSCB has a record of pharmacy confirmation that the actions from the Beta blocker learning letter were completed? < completed by HSCB >	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Were the following communications and their recommendations shared with and discussed by relevant staff? <ul style="list-style-type: none"> <li>• MSM newsletter with information on risks about incorrect selection of beta blockers (August 2013)?</li> <li>• Beta blocker learning letter (May 2014)?</li> <li>• Further dispensing errors involving beta blockers letter (July 2015)?</li> <li>• Learning from Serious Adverse Incident (February 2017)</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No		

<p>Did you make any changes or consider changes to practice as a result of the letter i.e.</p> <ul style="list-style-type: none"> <li>• Changes to the storage of beta blockers (separate area or/shelf edging),</li> <li>• Added an alert to the computer to highlight drugs which have the potential to be mis-selected,</li> <li>• Consideration of packaging in procuring generic medicines?</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No		
<p>Have you identified any further learning points which could be shared with others e.g. following an incident involving beta blockers in the pharmacy or as a result of discussing the recommendations in HSCB communications?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No		

### Guidance Notes

Medicines Safety Matters Newsletter (August 2013)

<http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-community-pharmacists/>

HSCB/PHA Safety and Quality Learning Letter: Dispensing Beta Blockers – Selection Errors (May 2014) <Copy enclosed by HSCB>

HSCB Urgent communication: Further Dispensing Errors involving Beta blockers (July 2015) <Copy enclosed by HSCB>

HSCB Learning from Serious Adverse Incident (February 2017) <http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-community-pharmacists/>

**Pharmacy Representative/s present:**

**Name**

**Job Title**

**HSCB Representative/s present:**

**Name**

**Job Title**

**Date**

Email included on the Assurance Declaration \_\_\_\_\_

Report to be sent by email/post (delete as appropriate) to: \_\_\_\_\_

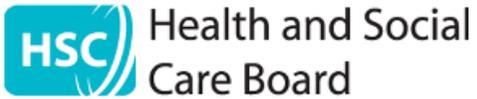
**References**

The Terms of Service are set out in <http://www.legislation.gov.uk/nisr/1997/381/contents/made>

Pharmaceutical Society of NI Standards <http://www.psni.org.uk/about/code-of-ethics-and-standards/>

HSC Dispensing Service Specification <http://www.hscbusiness.hscni.net/services/2652.htm>

**Appendix 4 Action Plan**



**Assurance Framework Visit Action Plan**

Name of contractor ..... Contractor No .....

Address of premises (including postcode).....

Action Point	Timescale for completion	Completed Y/N	Pharmacy comments

I confirm that the above action points have been completed:

Signature (Contractor or duly authorised signatory) .....

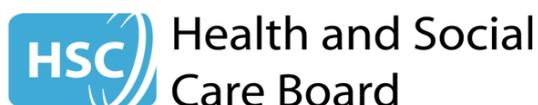
Name .....PSNI registration number .....

Position ..... Date .....

**Please return copy or email to HSCB <local address &email address> by <insert date>**

**HSCB USE** Action plan accepted Y / N

HSCB Adviser Signature ..... Date.....



## **REGIONAL PROFESSIONAL PANEL**

### **REMIT AND CONSTITUTION OF BUSINESS**

#### **1.0 Introduction**

- 1.1** With the establishment of the Health & Social Care Board (HSC Board) on 1 April 2009 there was a need to amend the clinical governance arrangements, which had served the legacy Boards for the management of concerns about performance for each of the four family practitioner services (FPS), in order to reflect the regional remit of the HSC Board. The four FPS include general medical, dental, community pharmacy and optometry.
- 1.2** In January 2011 the HSC Board implemented a single core process for managing concerns regarding any FPS practitioner. The purpose was to deliver a more consistent and effective approach to the management of cases, both across the geography of the region and between the four family practitioner services.

#### **2.0 The Role of the Regional Professional Panel**

- 2.1** The Regional Professional Panel (RPP) which became operational on 1 January 2011 is the collective name for four panels which meet to review performance concerns across the four services.
- 2.2** The professional membership of the RPP varies according to which FPS practitioner case is under review but lay members remain the same for all four panels.

#### **3.0 Terms of Reference**

- 3.1** The RPP is not an executive decision-making body, its role is advisory and is broadly contained in the following functions:
- 1) Assess relevant expressions of concern about underperformance of FPS Practitioners;
  - 2) Establish degree of seriousness of concerns and decide if further investigation or action is required;

- 3) Make recommendations including:
  - a. Support for practice infrastructure;
  - b. Retraining of contractors;
  - c. Clinical supervision/mentoring;
  - d. Referral to NCAS
  - e. Referral to other agencies (via Reference Committee/Chief Executive)
- 4) Advice on who leads on investigations and also joint investigations for example in the case of pharmacy concerns about dispensing errors;
- 5) Report its conclusions and recommended actions;
- 6) Reports to be shared with the Board's Reference Committee in serious cases and nominated officers in the HSCB as appropriate.
- 7) Follow up on all onward referrals of contractors by the Reference Committee to professional bodies, Police, HPSS Tribunal
- 8) Ensure that all cases are satisfactorily concluded.

#### **4.0 Composition**

##### **4.1 Membership of the RPP comprises lay and clinical representation:**

- Chair: Director of Integrated Care (or deputy)
- Professional Adviser from HSCB (case officer)
- Representative of GP, dental, pharmaceutical, optometric representative bodies as appropriate
- Representative of relevant Royal College/Pharmaceutical Society etc.
- The Director for Postgraduate General Practice Education and the Postgraduate Dental Dean from the NI Medical & Dental Training Agency
- Representative from Patient & Client Council
- Two user representatives from the membership of LCGs

##### **4.2 Board officers and the representatives from the NI Medical and Dental Training Agency shall be appointed for the period for which they hold the posts in their organisations.**

##### **4.3 Other members will be appointed for a period of 3 years, with an option to extend tenure for a further two years, or for the period agreed by their respective organisations where it does not exceed a five year period.**

##### **4.4 Representatives from Royal Colleges/Societies/ representative bodies:**

- GP, Optometry and Dental, will have to be on the relevant FPS list held by the Board; and
- CPNI and NICPLD, will have to be registered with the Pharmaceutical Society NI

on the date they take up membership of the Panel.

**4.5** The appointment of members who are not Board officers can be extended for a period of 6 months in circumstances where a nomination from their respective organisations is not made before the end of their term of office.

**4.6** The Panel will have access to legal advice as and when required.

## **5.0 Conduct Of Business**

**5.1** Agenda and briefing papers should be prepared and circulated in sufficient time to enable members to give them due consideration.

**5.2** Where the Panel was required to make a decision, the quorum would consist of a representative from the professional body, Chair of the Panel and a lay representative.

**5.3** The Panel shall provide an annual report to the HSCB's Senior Management Team and Governance Committee.

## **6.0 Declaration of Interest**

**6.1** Any member who had a relevant association with a practitioner about whom a concern is raised and which is to be considered at the meeting, must declare their interest and withdraw from the meeting.

**6.2** Where a member felt there may be a perceived conflict, it should be declared. They may wish to consider withdrawing from the meeting but would not be obliged to do so.

**6.3** If a member has any doubt about the relevance of an interest this should be discussed with the Panel. In the case of disagreement the decision of the Chairperson shall be final.

## **7.0 Frequency Of Meetings**

**7.1** The RPP will meet on a monthly basis, where required.



**Health and Social  
Care Board**

**Community Pharmacy Assurance Framework  
Visit Claim Form**

**Pharmacy Name:**

**Address:**

**Contractor No:**

**Contact Tel No:**


I wish to claim the sum of **£150** for the Community Pharmacy Assurance Framework Visit which has been undertaken in line with arrangements as set out in the Framework.

**Declaration by Contractor / Superintendent / Community Pharmacist / Duly Authorised Signatory**

**Name:** .....

**Signed:** ..... **Date:** .....

**For Office Use Only**

**Payment Authorisation**

I confirm that the above visit to which this claim relates to is legitimate charges against the Board and that the claim is in order for payment.

<b>Amount Authorised for Payment:</b>	<b>£150.00</b>
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**Signed:** ..... **Date:** .....

*(HSCB Local Office DoIC ABSM)*

<b>Cost Centre: J9FP05</b>	<b>Account Code: 194B4208</b>
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Please complete the above details and return to the appropriate local office for payment:-

<b>North</b>	Edith McMullan, Assistant Business Support Manager, HSCB North Office, County Hall, Ballymena, BT42 1QB
<b>South</b>	Andrew Gregg, Assistant Business Support Manager, HSCB South Office, Tower Hill, Armagh, BT61 9DR
<b>South East</b>	Sean Woods, Assistant Business Support Manager, HSCB South East Office, 12-22 Linenhall St, Belfast BT2 8BS
<b>West</b>	Tom Coyle, Assistant Business Support Manager, HSCB West Office, Gransha Park House, Clooney Rd, Derry BT47 6FN
<b>Belfast</b>	Denise Taylor, Assistant Business Support Manager, HSCB Belfast Office, 12-22 Linenhall St, Belfast BT2 8BS

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## References

<sup>i</sup> Dispensing Service Specification

<http://www.hscbusiness.hscni.net/services/2652.htm>

<sup>ii</sup> Pharmaceutical Services Regulations (NI) 1997

<http://www.hscbusiness.hscni.net/services/2539.htm>

<sup>iii</sup> Pharmaceutical Society of NI Standards

<http://www.psn.org.uk/about/code-of-ethics-and-standards/>