Appendix E: Application for inclusion in a pharmaceutical list at Ground Floor Flat 1, 4 Hambridge Road , RG14 5SS in respect of distance selling premises by Halo Pharmacy Limited

Our Ref: ME3064-CAS-260244-Y0T4Q2
To be quoted on all future correspondence

Primary Care Support England
PCSE Enquiries, P O Box 350
Darlington, DL1 9QN
Email pcse.pharmacyproject@nhs.net
Phone 0333 014 2884

Sent via email to all interested parties on the distribution list

6th February 2024

Dear Sir/Madam,

Re: Application for inclusion in a pharmaceutical list at Ground Floor Flat 1, 4 Hambridge Road, Newbury RG14 5SS in respect of distance selling premises by Halo Pharmacy Limited

We have received the above application, a copy of which is enclosed, and Buckinghamshire, Oxfordshire and Berkshire West ICB has completed its preliminary checks. We are now notifying interested parties of the application.

If you wish to make written representations on this application, they should be sent to me at the above address within 45 days of the date of this letter i.e. by 22nd March 2024. You should note that any comments submitted will be shared with other interested parties and the applicant and may be shared under the Freedom of Information Act as requested.

Buckinghamshire, Oxfordshire and Berkshire West ICB will consider all representations that are received and will arrange an oral hearing to determine the application if it identifies a matter on which it wishes to hear further evidence.

Please ensure you include our reference (see above) in the subject line of your email as this will help us file your representations with the correct application as quickly as possible.

I can confirm that no information that has been received in relation to this application is being withheld under paragraph 21(4), Schedule 2 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

NHS England

Primary Care Support England

Yours sincerely,

Andrew Cooper

Andrew Cooper
Pharmacy Market Administrative Services Officer

NHS England's Privacy Notice describes how we use personal data and explains how you can contact us and invoke your rights as a data subject. We will protect your information in line with the requirements of the Data Protection Act 2018.

Interested parties list:

Organisation Name	Address1	Address2	Address3	Address4	PostCode
Applicant					
Boots	4-5 NORTHBROOK STREET	NEWBURY	BERKSHIRE		RG14 1DJ
DAY LEWIS PHARMACY	G FLOOR UNIT, ACCESS HSE	STRAWBERRY HILL ROAD	NEWBURY	BERKSHIRE	RG14 1GE
Boots	UNIT 13 NEWBURY RETAIL PK	PINCHINGTON LANE	NEWBURY	BERKSHIRE	RG14 7HU
TESCO INSTORE PHARMACY	TESCO EXTRA	PINCHINGTON LANE	NEWBURY	BERKSHIRE	RG14 7HB
Wash Coomon Pharmacy	1 Monks Lane		NEWBURY	BERKSHIRE	RG14 7RW
Boots H/O					
Day Lewis H/O					
Tesco H/O					
Thames Valley LPC					
Thames Valley LMC					

West Berkshire HWB					
West Berkshire Healthwatch					
Commissioning Board					

Chapter 18

Annex 1

Application Form

Application in respect of distance selling premises

Defined as "listed chemist premises, or potential pharmacy premises, at which essential services are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises." Only pharmacy contractors may apply to open distance selling premises.

Application for inclusion in a pharmaceutical list for the area of

West Berkshire (name of health and well-being board).

This is an application in respect of distance selling premises and as such is an excepted application under regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the Regulations).

Please complete this form as legibly as possible.

Applicants should note that information provided in this form may be disclosed where this application is required to be notified to other parties or in response to a request made under the Freedom of Information Act 2000. Applicants are referred to paragraph 21 of Schedule 2 of the Regulations which sets out NHS England or the relevant delegated integrated care board's responsibilities in relation to information provided in this application form which an applicant advises is confidential.

1 Information regarding the applicant

1.1 Full name and correspondence address of the applicant

This is the name of the legal entity applying, not the person who is completing the application.

HALO PHARMACY LIMITED 197-199 Gulson Road,Coventry,CV1 2HZ

Is this a personal address? Yes ☐ No ☑

1.2 Applicant's legal entity

I/we am/are applying as a:

(Please tick relevant box. Only one box may be selected. GPhC/PSNI registration numbers only need to be provided for pharmacy applications.)

Sole trader ☐ **My GPhC/PSNI registration number is**

Partnership ☐

Please list each partner and their GPhC/PSNI registration number:

Corporate Body ☑

Superintendent's name and GPhC registration number is	Mr. Philip Obomighie 2067022

1.3 Provision of fitness information required by Part 1, Schedule 2 of the Regulations

(Please tick relevant box)

I/We have provided the required fitness information on a previous occasion to NHS England or the relevant delegated integrated care board or, before 1 April 2013, to a home primary care trust, and there is no missing information. I confirm that the previously provided information remains up-to-date and accurate. ☑

Please set out below when and to whom the information was provided. If NHS England or the relevant delegated integrated care board cannot locate the information previously supplied after using reasonable efforts to locate it, you will be asked to provide it again.

See Ref: CAS-214984-S1W3F7 - CHANGE OF OWNERSHIP OF FTJ67 (LLOYDS PHARMACY) TO FJ120 (HALO PHARMACY)

I/We have already provided the fitness information on a previous occasion to NHS England or the relevant delegated integrated care board or, before 1 April 2013, to a home primary care trust, but there is missing information. I confirm that the remainder of the previously provided information remains up-to-date and accurate. ☐

Please indicate what information NHS England or the relevant delegated integrated care board already has and when and to whom it was provided, and confirm the missing information that is being provided. If NHS England or the relevant delegated integrated care board cannot locate the information previously supplied after using reasonable efforts to locate it, you will be asked to provide it again.

I/We have provided the required fitness information with this application. ☐

1.4 Relevant fee

I/we include the relevant fee for this application. ☐

2 Address of the proposed premises

A full address must be provided – 'best estimates' are not acceptable. The regulations do not allow the premises to be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

Ground Floor Flat 1, 4, Hambridge Road , Newbury , RG14 5SS

These premises are currently in my/our possession*

* by rental, leasehold or freehold

Yes ☐ No ☑

3 Opening hours

3.1 Proposed core opening hours

Core opening hours must total 40 hours per week.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
10:00 - 18:00	10:00 - 18:00	10:00 - 18:00	10:00 - 18:00	10:00 - 18:00	Closed	Closed	40:00

3.2 Total proposed opening hours

The total opening hours includes the core hours and any supplementary opening hours.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
10:00 - 18:00	10:00 - 18:00	10:00 - 18:00	10:00 - 18:00	10:00 - 18:00	Closed	Closed	40:00

4 Pharmaceutical services to be provided at these premises

Essential services (paragraphs 3 to 22, Schedule 4) ☑

If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none', if it is intended that the pharmacy will not provide appliances).

Please give details of any advanced and enhanced services you intend to provide.

Please note that enhanced services are those commissioned by NHS England or the relevant delegated integrated care board. Do not include services which are commissioned by the local authority/council or any other commissioner.

Whilst advanced and/or enhanced services can be provided at the premises, this must not involve the provision of complementary essential services related to the advanced or enhanced service. For example, a supervised consumption enhanced service for methadone would require the pharmacy to dispense the methadone for consumption, and therefore a supervised consumption enhanced service cannot be provided from the premises as that would require the corresponding dispensing essential service to be provided to persons present at the pharmacy which is prohibited under the distance selling exception.

These details should include:

- confirmation that you are accredited to provide the services where that accreditation is a prerequisite for the provision of the services;
- confirmation that the premises are accredited in respect of the provision of the services where that accreditation is a prerequisite for the provision of the services; and
- a floor plan showing the consultation area where you propose to offer the services, where relevant. Where a floor plan showing the consultation area cannot be provided please set out the reasons for this.

Service	**Accredited to provide (Y/N/NA)**	**Premises accredited (Y/N/NA)**
New medicine service (NMS)	Y	Y
Community Pharmacy Seasonal Influenza Vaccination	Y	Y
Community Pharmacist Consultation Service (CPCS)	Y	Y
Care Home Service	Y	Y
Home Delivery Service	Y	Y
On Demand Availability of Specialist Drugs Service	Y	Y

Floor plan showing consultation area

Floor plan_Hambridge road.pdf

5 Applications in relation to premises that are in close proximity to other listed chemist premises

This section should only be completed if the premises included in section 2 above are adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

In my/our view this application should not be refused pursuant to Regulation 31 for the following reasons:

6 Information in support of the application

6.1 Proposed premises that are on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

This section should only be completed if the premises included in section 2 above are on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

In my/our view this application should not be refused pursuant to Regulation 25(2)(a) for the following reasons:

7 Pharmacy procedures

7.1 Please explain how the pharmacy procedures used within the premises will secure:

(a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and

(b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

7.2 Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.

7.3 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services.

You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.

Essential Services will provided remotely through the deployment of an approved Website and Patient App such as to enable any patient anywhere in England to request NHS Essential services without a face to face contact. The website + App + all other digital platforms for communication will be available uninterrupted at least during the opening hours of the premises.
2. Please see SOPs attached. These provide the overall framework for the provision of essential services in the Pharmacy.
3. Only advanced services that can be provided remotely will be provided. The pharmacy does not intend to provide services that could require service users to come to the premises.
3.2 Request for face-to-face service provision
If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any Essential Service face to face on or in the vicinity of the premises then they must;
 Inform the person that no face-to-face contact may occur between the patient or their representative and any member of staff.
 Provide the person with a copy of our patient information leaflet that explains what services the pharmacy provides and why they cannot be carried out face-to-face.
 Refer the person to the Responsible Pharmacist if they require any further explanation.
 Establish where the person is located in England and which services they require.
 Explain that due to NHS Regulations we are unable to provide face-to-face provision of NHS Essential Services.
 Use the NHS Choices website to find suitable service providers near to the patient and offer them their details to contact them (note this is not "signposting" as an NHS service and is simply providing proper patient care in accordance with GPhC standards).

8 Undertakings

By virtue of submitting this application I/we undertake to notify NHS England or the relevant delegated integrated care board within 7 days of any material changes to the information provided in this application (including any fitness information provided under paragraph 3 or 4, Schedule 2) before:

- the application is withdrawn,
- while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
- if the application is granted, I/we commence the provision of the services to which this application relates,

whichever is the latest of these events to take place.

I/We also undertake to notify NHS England or the relevant delegated integrated care board if I/we am/are included, or apply to be included, in any other relevant list before:

- the application is withdrawn,
- while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or
- if the application is granted, I/we commence the provision of the services to which this application relates,

whichever is the latest of these events to take place.

I/We also undertake:

- to comply with all the obligations that are to be my/our terms of service under Regulation 11 if the application is granted, and
- in particular to provide all the services and perform all the activities at the premises listed above that are required under the terms of service to be provided or performed as or in connection with essential services.

The following only applies where the applicant is seeking to provide directed services. I/We:

- undertake to provide the directed services mentioned in this application if they are commissioned within 3 years of the date of grant of this application or, if later, the listing of the premises to which this application relates,
- undertake, if the services are commissioned, to provide the services in accordance with an agreed service specification, and
- agree not to unreasonably withhold my/our agreement to the service specification for each directed service I/we are seeking to provide.

I confirm that to the best of my knowledge the information contained in my/our application is correct.

Name .....

Position .....

Date .....

On behalf of the company/partnership .....

Contact phone number in case of queries .....

Contact email number in case of queries .....

Registered office

Please send the completed form to:

Email: PCSE.marketentry@nhs.net

Post: Primary Care Support England, PO Box 350, Darlington, DL1 9QN

Chapter 29

Annex 11

Distance Selling Premises Application

Application by Halo Pharmacy Ltd (the applicant) to open a distance selling premises at Ground Floor Flat 1, 4 Hambridge Road, Newbury RG14 5SS

Explanatory notes by Buckinghamshire, Oxfordshire and Berkshire West ICB

1. What is this application for?

The applicant wishes to open an NHS internet pharmacy at Ground Floor Flat 1, 4 Hambridge Road, Newbury RG14 5SS. This type of pharmacy is referred to as 'distance selling premises' in the regulations and operates under strict rules which means it is not able to provide services face to face at the premises.

A pharmacy can only give patients medicines prescribed by NHS GPs if it has Buckinghamshire, Oxfordshire and Berkshire West ICB's permission. We give permission for this type of pharmacy where we are satisfied that they will be able to provide services safely and effectively without seeing the patient face to face. This type of pharmacy provides the same services as any other type of pharmacy but you can't, for example, take your prescription there to be dispensed or collect it once it has been dispensed. Instead you could post it to the pharmacy or ask your GP to send it electronically. The pharmacy would then dispense it and send it to you either via the post or a courier.

These notes explain the process we follow when deciding whether to give permission.

2. Why have I been sent a copy of the application?

You are being invited to make comments on the application before Buckinghamshire, Oxfordshire and Berkshire West ICB takes a decision on whether the pharmacy can go ahead. Any comments must be received before the end of the 45-day period mentioned in the letter.

Applications are not confidential. If you want, you may share details with anyone else who might be interested. They can also make comments within the same 45-day period.

Any comments we receive will be sent to the applicant. They will have a chance to respond to us about those comments.

When we come to make a decision, Buckinghamshire, Oxfordshire and Berkshire West ICB will consider any comments it has received and any response to those comments from the applicant.

3. How will Buckinghamshire, Oxfordshire and Berkshire West ICB decide whether to give permission for a new pharmacy?

Firstly we need to check to make sure the applicant is offering to provide services to anyone in England who may want to use them.

Then we look at how they say they will provide services without seeing the patient face to face. We need to check to make sure they are able to provide all the services you would expect from a pharmacy safely and effectively.

4. When will a decision be made?

We expect to make a decision by 10 March 2023.

5. What will happen if permission is given?

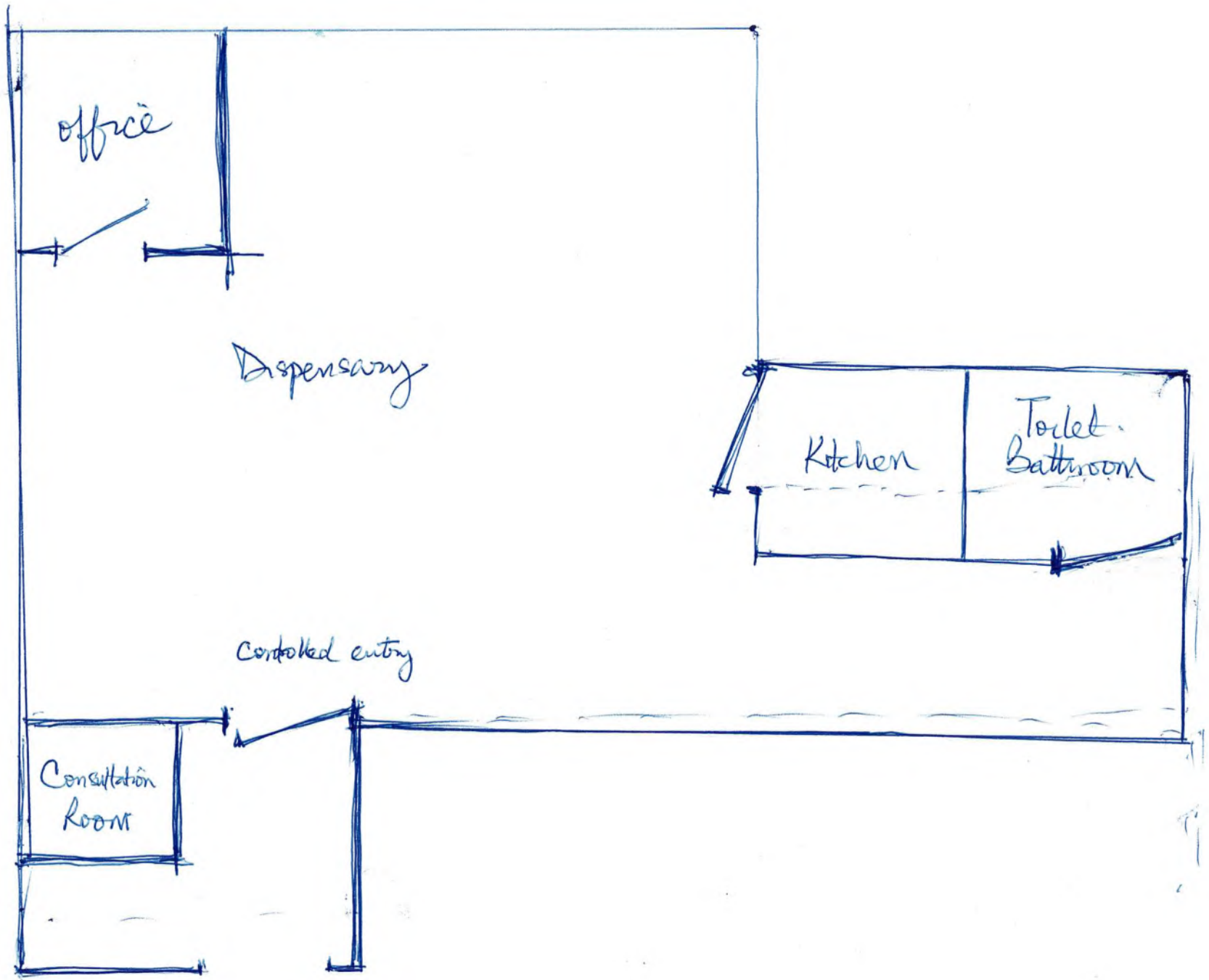
If we decide to give permission for the pharmacy to open, this does not automatically mean that it will happen. Other local pharmacies may be able to appeal against the decision. Appeals are dealt with at national level by NHS Resolution.

If no appeals are received or if they are rejected by NHS Resolution, the applicant would then have up to 12 months to open, although this could be extended to 15 months. If those deadlines were not met, then the permission would expire.

6. What if permission is refused?

The applicant would be able to appeal.

NHS England's Privacy Notice describes how certain services are provided on behalf of Integrated Care Boards and how personal data is used. It also explains how you can invoke your rights as a data subject. We will protect your information in line with the requirements of the Data Protection Act 2018.


office
Dispensary
Kitchen
Toilet.
Bathroom
Controlled entry
Consultation
Room

Dispensary Standard Operating Procedures

DISTANCE SELLING PHARMACY BRANCH

[Note: This is not a complete list of SOPs for the operation of the pharmacy. These SOPs are provided to demonstrate how essential services will be provided in a safe and effective manner without face-to-face contact with the patient.]

DOCUMENT CONTROL SHEET

Title	Standard Operating Procedures
Authorised by	…… (Superintendent)
Approvals	…… (Superintendent)
Distribution	[HALODIRECT – PHARMACY]
Filename	Dispensary Standard Operating Procedures

DOCUMENT AMENDMENT HISTORY

A list of amendments made to these SOPs is available at the end of this document

CONTACT DETAILS

For further information contact:

PHILIP OBOMIGHIE

Tel:

Mob:

E-mail:

TABLE OF CONTENTS

1. Introduction and Background to SOPs

Standard Operating Procedures (SOPs) are a written process that assures that good standards of Clinical Governance are achieved. The processes should be reviewed regularly with the aim of continually improving the working practice in the pharmacy and ensuring that it is a safe working environment.

It is the responsibility of each individual carrying out duties and using the SOPs to ensure that they understand the SOPs thoroughly and seek clarification from the Responsible Pharmacist (RP) where necessary. It is the responsibility of the RP to ensure that the SOPs are being adhered to and understood by all staff members using those SOPs. The RP must ensure competency is attained for the relevant SOPs before approval for using a particular SOP by staff members. Any amendments of the SOPs due to changes in contracts or the occurrence of any serious incidents should be reported to the Superintendent Pharmacist in writing, using the appropriate amendment form. Overarching responsibility of the content of the SOPs is that of the Superintendent Pharmacist.

The GPhC has set out principles for the purpose of creating and maintaining the right environment for Pharmacy staff to abide by, to ensure Pharmacies are safe and effective in their practice.

- **Principle 1:** The governance arrangements safeguard the health, safety and wellbeing of patients and the public.
- **Principle 2:** Staff is empowered and competent to safeguard the health, safety and wellbeing of patients and the public.
- **Principle 3:** The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.
- **Principle 4:** The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.
- **Principle 5:** The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

In this document and SOPs, the pharmacy is referred to as “The Pharmacy”.

IMPORTANT NOTE RE GPHC GUIDANCE

THESE SOPS COVER THE PROVISION OF ESSENTIAL SERVICES UNDER THE NHS (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) REGULATIONS 2013 (AS AMENDED). GPHC GUIDANCE ON THE PRESCRIBING AND DISPENSING OR CERTAIN CLASSES OF MEDICINES TO PATIENTS WILL BE RELEVANT TO ANY PRESCRIBING OR SUPPLY VIA PRIVATE PRESCRIPTION OR VIA ONLINE CONSULTATIONS, BUT THIS DOES NOT FORM PART OF THE REGULATIONS FOR THE DISPENSING OF NHS PRESCRIPTIONS AND IS NOT INCLUDED WITHIN THESE SOPS.

1.1 Risk Assessment

There are different risks with providing any pharmacy service at a distance, including on the internet. The Pharmacy has a Risk Assessment which identifies risks and scores those risk (likelihood / impact score) to produce a Risk Matrix. The Risk Assessment does not form part of the SOPs, but feeds in to the content of the SOPs. Each review of the SOPs must be undertaken along with a review of the Risk Matrix.

1.2 Regular Audit

The Audit document does not form part of these SOPs, but should be referred to by the RP and Superintendent as part of any update.

The Audit document deals with:

- staffing levels and the training and skills within the team
- suitability of communication methods with patients, and between staff and other healthcare providers
- systems and processes for receiving prescriptions, including EPS.
- records of decisions to make or refuse a sale.
- systems and processes for secure delivery to patients
- information about pharmacy services on the website
- how to keep to the information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law
- feedback from patients and people who use our pharmacy services.
- concerns or complaints received, and
- activities of third parties, agents or contractors

1.3 Overriding Provisions Applicable to All SOPs

These SOPs are written in accordance with the requirements of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, 'the 'Regulations'.

All pharmacy staff must note that this pharmacy operates in accordance with specific approval under the Regulations and these premises are 'Distance Selling Premises'. In order to comply with our terms of service, this pharmacy will provide;

- The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.
- The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises.

All staff must receive induction and training which includes training in the specific terms of service of Distance Selling pharmacies.

All staff must receive training that includes the provision of Essential Services and covers:

- Dispensing Medicines
- Clinical Governance
- Signposting
- Dispensing Appliances (NB if applicable only)
- Repeat Dispensing
- Promotion of Health Lifestyles
- Support for Self-Care
- Emergency Supply

- Discharge Medicines Service
- SOPs as set out in this document.

All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential Services either on or in the vicinity of the premises.

Face to face contact with patients or their representatives either on or in the vicinity of the premises is only allowed in respect of the provision of services other than Essential Services.

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises.

Where any SOP could be considered to imply that face-to-face contact with a patient or their representative may take place either on or in the vicinity of the premises, then this should be immediately referred to the Responsible Pharmacist (RP) before any further action is taken.

If the RP receives a query from any member of staff as detailed above, they must:

- Inform the member of staff that no face-to-face contact may occur between the patient or their representative and any member of staff either on or in the vicinity of the premises.
- Review the relevant SOP and consider whether or not any part of the wording should be changed to ensure that the obligations applicable to Distance Selling Pharmacies are adhered to.

1.4 NHS Mail, NHS.uk Entry and the NHS Digital Directory of Services

It is common for secure communication from NHS bodies to now be received via NHS mail. This includes notification of Market Entry applications and referrals for services such as the Discharge Medicines Service. It is therefore important that the NHS mail system is accessible and accessed every day by staff.

At least two members of staff (unless fewer than two are working at the pharmacy) must have live, linked NHSmail accounts to the premises specific NHSmail account. NOTE – the NHSmail account is not the same as the email address that may be set up by the pharmacy themselves and is assigned by NHSmail directly.

When the NHSmail account details are received for the first time the Pharmacy must register the email address with the MHRA so that Central Alerting System emails can be received on product defects / recalls.

The NHS Digital Directory of Services contains a profile for the pharmacy and the pharmacy must verify and update it at least once per quarter to ensure that the information contained in the profile is comprehensive and accurate. Diary notes should be made on the computer system to ensure this is done.

Similarly, the NHS.uk profile must be kept comprehensive and accurate and verified and updated at least once per quarter. The Pharmacy should carry this out at the same time as verifying / updating the NHS Digital Directory of Services.

NHSmail must be checked frequently and in any even not less than 3 times per day on days that the pharmacy is open.

2. Our "Healthy Living Pharmacy"

We will operate as a healthy Living Pharmacy ("HLP").

The Superintendent Pharmacist will provide support and training to all staff members as part of our commitment to HLP.

Training will develop the pharmacy team skills so that all members of staff understand their role in pro-actively promoting health and wellbeing messages.

As a HLP we look to engage with both the community that we serve and the commissioner of our NHS services.

We take part in health promotion which is led by commissioners (such as NHS England, the CCG or the local authority) as well as promoting a healthy lifestyle message to our patients and signposting them to other relevant services when we can.

We have a "Health Promotion Zone" on our website and also provide healthy living advice on an opportunistic basis to patients.

3. Procedures for NHS Essential Services

NHS Essential Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflets. Any patient who approaches the Pharmacy at any time for an NHS Essential service will directed and signposted appropriately to use a non-face to face method.

3.1 Communication Channels

All communication regarding NHS Essential Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages.

The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises.

3.2 Request for face-to-face service provision

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any Essential Service face to face on or in the vicinity of the premises then they must;

- Inform the person that no face-to-face contact may occur between the patient or their representative and any member of staff.
- Provide the person with a copy of our patient information leaflet that explains what services the pharmacy provides and why they cannot be carried out face-to-face.
- Refer the person to the Responsible Pharmacist if they require any further explanation.
- Establish where the person is located in England and which services they require.
- Explain that due to NHS Regulations we are unable to provide face-to-face provision of NHS Essential Services.
- Use the NHS Choices website to find suitable service providers near to the patient and offer them their details to contact them (note this is not “signposting” as an NHS service and is simply providing proper patient care in accordance with GPhC standards).

3.3 Provision of Advanced or Enhanced Services

Any advanced or enhanced services provided by the Pharmacy will be such that can only be done remotely using the same identification and communication methods as described for the provision of Essential services without patients accessing the service at the premises.

3.4 Summary Care Record Access

The pharmacy has access to Summary Care Records via our system supplier. When delivering any essential service the pharmacy should, If appropriate, access the patient’s Summary Care Record to see if it assists in providing the service

To obtain consent to access the summary care record you can:

- ask the patient directly each time
- get extended permission to view – useful for patients with repeat prescriptions
- get permission to view by proxy – useful for care home patients

(check with RP for most suitable procedure)

4. The Equality Act

Information in this section is taken from the PSNC Briefing Note on the Equality Act with additional wording specific to this pharmacy.

The Equality Act 2010 sets out a framework which requires providers of goods and services, not to discriminate against persons with a disability.

The first matter to consider is whether the patient has a disability. A person is regarded as being disabled, if they have a physical or mental impairment which has a substantial adverse effect on that person's ability to carry out day to day activities. The impairment must be either long term (that is, has lasted more than 12 months) or is expected to last more than 12 months or for the rest of the person's life (for example multiple sclerosis).

The legislation does not require a provider to carry out an assessment under the Equality Act – all that is required, is that the provider makes a reasonable adjustment, if this is what is needed in order to allow the person to access the service.

4.1 What do I need to Consider?

Whenever you are providing any service to a patient you should consider whether there is a reasonable adjustment that you can make that could remove or overcome any obstacle that the patient has to accessing services.

If a person is disabled, you must consider whether a feature of the way in which you provide the service means that the disabled person would not be able to access the service, whereas a non- disabled person would. For example, a patient with severe arthritis, who is unable to open child resistant containers, would be unable to access their medicines if all medicines supplied by the pharmacy are in child resistant containers.

The provider of the service must then consider whether any adjustment could be made, which would have the result of overcoming the obstacles to accessing the service. In this example, providing an easy open container would overcome the obstacles to accessing medicines. An alternative would be to ensure that there is a care worker available to open the child resistant container every time the patient is due to take a dose.

The provider will be in breach of the legislation if there is a reasonable adjustment available which he chooses not to make, causing the person to be unable to access the service. In the above example, it would be unreasonable for the pharmacist to provide a care worker to visit the patient to help with opening the containers, but it would be reasonable to expect the pharmacist to dispense medicines in an easy open container.

4.2 Practical ways of supporting patients

The majority of patients, including patients in a care home where professional care workers are engaged to assist with medication, do not require any additional support to enable them to access medicines. Patients with a disability may be able to access their medicines without additional support but for some, the pharmacist will need to make adjustments to overcome obstacles to the use of the service.

Before assuming that the patient requires an adjustment, it is important to establish from the patient, what their personal preferences are; it should not be assumed that a patient who has a disability wants a particular adjustment. Discussing the benefits and shortcomings of particular adjustments with the patient will allow the patient to reach their own decision.

Easy open containers and large print labels are common adjustments. For patients who are forgetful, a reminder chart, showing which medicines are to be taken at particular times during the day may assist – but the pharmacist would need to ensure the patient understands how the reminder chart works, and is able to use it correctly.

It is likely that requests for MDS will be made from a wider group of patients, and their carers / relatives, because of the convenience that MDS brings. Whilst there is no funding available from the NHS for MDS

our policy is to provide MDS free of charge to any patient who requests it and where the pharmacist believes that MDS is a reasonable adjustment that would overcome an obstacle to accessing services.

Whichever adjustment is made to assist patients with a disability, it is essential that the pharmacist satisfies himself that the patient is able to understand and be able to benefit from the adjustment, without introducing additional risks. Therefore, if you have tried to explain an adjustment that you propose to make, but a patient does not understand that adjustment, then you should not proceed to introduce it as it would not effectively overcome the obstacle (i.e., it might solve one problem, but create another).

4.3 Patients who have care workers

Some patients have care workers engaged to provide support. The care worker may be engaged to assist the patient - in this case the care worker follows the directions of the patient receiving the care. For example, the patient would tell the care worker "I want a blue tablet and a green tablet" the care worker would help the patient to select the blue tablet and the green tablet. This may be appropriate if for example the patient is visually impaired, or if the patient has manual dexterity problems. If a care worker is engaged to assist the patient, the extent of this assistance will be recorded in the care plan.

Or the care worker may be engaged to administer the medicines – in this case the care worker makes the decision as to whether the patient needs medicines or not. To do this they must be able to read information whether that is from a reminder chart or the labels affixed to the medicine packaging. Administration does not necessarily mean putting the individual tablets into the patient's mouth. The key criterion is that it is the care worker who makes the decision as to whether there is a particular medicine due at a particular time. The patient may still be able to take the tablets from the packs themselves. If the care worker is engaged to administer the medicines, there will be a record made by the care worker of each administration.

The Care Quality Commission, the regulator of care worker organisations has two relevant standards linked to medicines. The key point from these outcomes is that the organisation providing the care worker must make sure they have sufficient staff with the right knowledge, experience, qualifications and skills to support the people that they are caring for.

If the care plan for the patient requires the care worker to ‘assist’ the patient as above, then the care worker should have the necessary skills to open containers, and hand the medicines to the patient (whether they are in MDS or original manufacturer’s containers). The care worker would not be expected to decide whether a particular medicine must be administered at the particular time.

If, however, the care worker is expected to administer medicines (as recorded in the care plan), then the care worker should have the qualifications and skills to be able to interpret instructions on the medicines container, whether that is an MDS or a manufacturer’s container that has been dispensed bearing the pharmacy dispensing label.

The skills that appear to be needed to administer medicines would include being able to read instructions on labels and interpret the dosage instructions.

The employer of the care worker should specify the boundaries as to whether the care worker will assist with or administer medicines and it is the obligation of the employer to ensure that the care worker has the requisite skills and qualifications to undertake the roles.

Carer organisations may benefit from seeking the assistance of a pharmacist to provide training to the care workers on interpreting dispensing labels, particularly for those care workers that are engaged to administer medicines. It should not be the case, that carer organisations simply rely on pharmacists to provide medicines in MDS as a matter of routine to lower the skills required of care workers.

If pharmacists believe that a patient has been provided with a carer who is not sufficiently skilled and qualified to provide the required level of support to the patient, then consideration ought to be given to using the raising concerns procedures (as required in the clinical governance section of the terms of service) to alert the Care Quality Commission.

5. Contacting Patients by Phone or E-mail

5.1 Objective

Information about patients that is confidential must not be disclosed without consent other than where there is a legal requirement to do so or in exceptional circumstances. Patients must also provide their informed consent to receive services from the pharmacy.

A number of policies are relevant and must be considered within the pharmacy. These include:

- The *Data General Data Protection Regulations (GDPR)*,
- *Data Protection Act 2018*
- the '*Human Rights Act 1998*',
- the '*Common Law Duty of Confidentiality*' (Appendix 2) and
- The Pharmacy's '*Clinical Governance Policy*' provides thorough guidance on the steps necessary to ensure patient confidential information is never disclosed without consent except, if required to do so by law or in exceptional circumstances.

This SOP ensures:

- Safeguards are in place to confirm the identity of the patient by whatever means of contact is used.
- Confidential information is not disclosed to persons who are not approved to receive it.
- Details of children's carers or vulnerable adult carers are properly collected and stored.
- Ensure confidential information is not sent via an unsecure or inappropriate manner (e.g., leaving messages on voicemail)
- Communication is recorded and kept up to date.
- Notes of outcomes are maintained and form an auditable trail of communication between the pharmacy and the patient.

5.2 The Caldicott Committee Report

Review of patient-identifiable information, 1997 listed the following identifiers (or a combination of these pieces of information) that are appropriate for identification of the patient.

- Surname
- Initials
- Date of birth
- Postcode
- Sex
- National Insurance number
- Forename
- Address
- Other dates (e.g., diagnosis)
- Occupation
- NHS number
- Ethnic group
- Local identifier (e.g., SH account No. hospital or GP practice number)

5.3 Scope

This SOP looks at the procedure for safely contacting patients without face-to-face confirmation of their identity.

5.4 Responsibility

Dispensers, Technicians, Administration staff, Company driver, Pharmacists and Responsible Pharmacist.

5.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

5.6 Risks

- Failure to properly identify the patient.
- Breach of confidentiality.
- Failure to secure consent prior to sharing confidential information.
- Incorrect of false information being provided.
- Communication difficulties (speech problems, language barriers).

5.7 Process

- Transactions can only be carried out following patient registration on the website or completing a paper registration form and posting back to the pharmacy. By registering, patients would provide consent to be contacted for the purpose of service provision.
- Upon registration, patients will be sent an automated e-mail confirming registration with the website and confirming their e-mail address.
- Patients have the opportunity to contact the Pharmacy if this information is incorrect and this allows a check of falsified information. (NB Also consider data protection issues)

5.8 Communication via e-mail/letter

Contact patients via their preferred method of communication where possible.

- Use the standard e-mail/letter template for communicating to patients to:
  - Advise of any delays in medication supply.
  - Advise when medicines are due for delivery.
  - Advise that patients may have their electronic prescription returned to the spine to be dispensed elsewhere if items are unavailable.
  - Advise about services, healthcare information or advice, promotional information or updates regarding services.
  - Sending a letter of apology following a complaint

These can be found in the company template folder.

Always record the date and details of any communication sent.

5.9 Communication via Phone / Live Audio

- There will be instances where you will need to speak with the patient, e.g.:
  - To advise of a clinical intervention.
  - To confirm when medication will be delivered.
  - To advise of a supply issue / medication delivery delay.
  - To investigate a complaint.
  - To confirm delivery address.
- Whenever contacting patients, have the patient's registration details to refer to.

- Prefix the phone number with 141, to withhold the Pharmacy phone number. This is not to protect the pharmacy's privacy, but to ensure that any person who sees the number on a phone screen cannot tell that the patient is receiving a call from the pharmacy.
- Ask to speak with the named person.
- Ask any combination of at least two of the security questions listed above as patient identifiers.
    - If you have any reason to doubt the identity of the patient, tell them that you will call back later and refer to the RP.
- If the patient is not there, tell the person who answers that you will call again later.
- Do not say who you are of where you are calling from until you are certain you are talking to the patient.
- Do not discuss the patient's details with any other person.
- Do not leave a voicemail indicating the purpose of your call.
- Do not leave a message about the patient's medication or order with another person unless the patient has given consent for this.
- Refer to the Responsible Pharmacist in situations where:
    - The patient has a carer.
    - The patient is unable to communicate on the phone.
    - There are any concerns about whether the person is the patient or their authorised representative.
- Log all conversations on the patient records, recording date and time and who you have spoken to and the details of the conversation.

5.10 Communication via Live Video

There will be instances where you will need to see the patient when speaking to them.

Whenever contacting patients, have the patient's registration details to refer to.

Check that you are speaking with the named person.

Ask any combination of at least two of the security questions listed above as patient identifiers.
- If you have any reason to doubt the identity of the patient, tell them that you will call back later and refer to the RP.

If the patient is not there, tell the person who answers that you will call again later.

Do not say who you are of where you are calling from until you are certain you are talking to the patient.

Do not discuss the patient's details with any other person.

Do not leave a message about the patient's medication or order with another person unless the patient has given consent for this.

Refer to the Responsible Pharmacist in situations where:
- The patient has a carer.
- The patient is unable to use the live video system.
- There are any concerns about whether the person is the patient or their authorised representative.

Log all conversations on the patient records, recording date and time and who you have spoken to and the details of the conversation.

6. Online Order Receipt & Exemption Checking

6.1 Objective

To capture all orders, to then process promptly and professionally to ensure:

- Patient details are complete and accurate on registration.
- The order on the administration screen matches with the original prescriptions once received.
- Prescription charges have been collected and processed where they are due.
- Prescription charge exemption is verified with scanned/posted evidence and records maintained.
- A message is sent to advise the patient the order has been received and is being dealt with
- Orders are all captured and not missed.
- Prioritising of orders by their despatch date. Dependent on the patients chosen delivery date.

6.2 Scope

All online services including the following:

- Healthcare products purchased online in their basket.
- Requests for dispensing Private Prescriptions.
- Requests to collect and dispense NHS Prescriptions.
- Requests to dispense a prescription received in the post.
- Any requests from the “contact us” section of the website.

6.3 Responsibility

Dispenser, Technicians, Administrative staff, Pharmacist and Responsible Pharmacist (RP).

6.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

6.5 Known Risks

- The payment process is not complete.
- Exemption details are not accurate.
- Prescription may be a forgery.
- Prescription is not received in the post.
- Technical issues with the online order processing.
- Inability to contact the patient.

6.6 Process

6.7 Order receipt

A patient consents to using our service by registering on our website.

Any orders received should be printed and will contain the following details:

- Full name
- Full address
- Date of birth
- Gender
- Tel. number
- E-mail address
- Ordered items from their basket
- Order reference (system generated)
- Customer Account Ref (system generated)

6.8 Pharmacists Checks

Check all details on the order are appropriate and legal.

- The Pharmacist is to perform an assessment of the WWHAM responses from the online questionnaire for all non-prescription medicine orders (GSL and P) along with registration details (age and gender) to use their professional knowledge and judgment to ascertain the appropriateness of the product wishing to be purchased.
- The supply of any medicine must be made either by or under the direct supervision of the pharmacist on duty.
- Make all necessary checks to establish whether the intended user is the person requesting the product.
- Consider if it is appropriate to access the patient's summary care record to consider the products ordered against the information contained within the summary care record.
- Ensure that PIL's are available for all the products and sufficient information is available to the intended user. If necessary, contact the patient by telephone or e-mail to gain further clarification of the symptoms and their understanding of the use of the product. If a product is not suitable for a patient explain the reasons and respond accordingly, either recommending an alternative product, or referring if necessary.
- Patients would receive a delivery note (Fig 1) with their despatched order, advising that the pharmacist can be consulted by contacting them by telephone or e-mail.
- Ensure that the product selected by the patient is suitable for the symptoms described.
- Check the items ordered are appropriate for the intended user, taking into consideration their age, gender, contraindications, online consultation notes, Sale of Medicines Protocol and supply of items with the potential of abuse. Take particular care with POM to P switches, quantities of product ingredients being purchased, particularly Paracetamol and Codeine. Refer to SOP 'Online supply of pseudoephedrine and ephedrine containing products' and SOP 'Pharmaceutical and Legal Assessment' for further guidance.
- For any interventions refer to SOP 'Interventions and Problem solving' for further guidance.
- For any product recommendations received through e-mail, or phone conversations; ensure that enough information (using WWHAM as a baseline) has been gathered to allow for an informed decision on choosing the most appropriate product to recommend.
- If the patient would benefit from a face-to-face consultation with a pharmacist, then refer the customer to the Signposting section of the website to advise them of the pharmacies in their area.
- The website has safeguards in place to avoid purchases of multiple P medicines, multiple pseudoephedrine or ephedrine containing products, etc. If the case arises of a need to refund due to unsuitability of treatment, credit the card used for the online purchase.

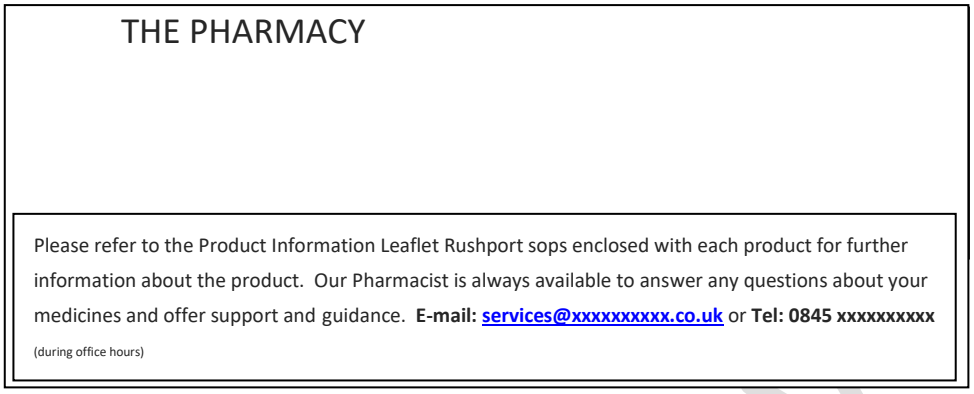


Fig 1. Sample of a Delivery Note (details TBC)

6.9 Prescription Order Processing

6.10 Administration Checks

- **Check all prescriptions received in the post against printed and written prescription reception forms.** Check the corresponding prescription has been received in the post and match with the received and printed order by confirming the unique voucher number, patient name, address and DOB.
- Prescriptions should be received within 5 working days. If the prescription has not been received within this period, then the patient should be contacted to ensure it has been posted. If the prescription has been lost in the post, the patient should contact their GP to obtain a new prescription.
- **Check the patient's details on the prescription**. They should include:
    - Full name
    - Address including postcode
    - Date of birth
    - If the wrong prescription has been received for a patient, then refer to the RP before contacting the patient.
    - If the prescription is illegible or missing details, then refer to the RP before contacting the prescriber.
- **Check the prescriber has signed the prescription and it is in date**. If the prescription is not signed or out of date, then refer to the RP and/or return the prescription to the surgery.
- **If the prescription is for Repeat Dispensing (RA/RD) ensure all information and forms are present and correct.** Ensure that the prescriber has signed the RA copy and that the correct number of RD copies is enclosed. Create a Repeat Dispensing file for the patient if this is their first batch of prescriptions or add it to their existing file.
- **Check to see if any items will require ordering**. Specials or unusual items may need to be ordered in and may take longer than the usual delivery time period. If this is the case, contact the patient to inform them of the reason for a possible delay and expected delivery date of their items.
- Contact the customer if their chosen delivery address cannot be found on the Royal Mail address search engine and refer to the RP if the address appears illegitimate.
- Check the payment details have been processed correctly for each transaction via the online payment system.
- For NHS Prescriptions where appropriate check the reverse of the prescription is completed correctly.

- Advise the patient that they may have their electronic prescription returned to the spine to be dispensed elsewhere if items are unavailable.

6.11 Exempt NHS Prescriptions

- The reverse of the prescription should be fully completed in black ink other than for age related exemptions where the age is printed on the prescription form.
- In order to secure exemption of or remission from prescription charges when presenting a prescription form to a pharmacy, or appliance contractor, the patient, or a person on his behalf, must complete the declaration on the back of the prescription form.
- If this is not the case or there is some information missing, then contact the patient to request missing information.
- Where patients do not have evidence or where there is doubt over whether the evidence provided is genuine or appropriate, the "Evidence not Seen" box on the back of the prescription should be marked with an X by pharmacy staff. Pharmacy staff should not refuse to dispense items on the basis that the patient does not provide evidence of their entitlement to free prescriptions.
- Where no satisfactory evidence of exemption has been provided patients should be informed that checks to prevent and detect fraud are routinely undertaken by the NHS.
- satisfactory evidence includes evidence derived from a check, known as a real time exemption check, of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under the Charges Regulations.
- Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.
- The PSNC advises that If a valid certificate of exemption has been provided as evidence, for example a medical exemption certificate or pre-payment certificate, and noted on the PMR along with the certificate's expiry date, it is not necessary to ask the patient to provide proof again within the validity of that certificate. Patients claiming exemption because they receive Income Support or Jobseeker's Allowance (income-based) should be asked to provide evidence on each occasion to ensure their continued entitlement.
- ensure that the required information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service (if either it is not already recorded in those records or a check, known as a real time exemption check, has not produced satisfactory evidence)

NOTE: Verification of Declarations of Prescription Exemptions

- Where a patient uses the postal system to provide evidence of exempt status then the patient should be advised to use Special Delivery Postal Services or our own courier service. The pharmacy should cover the cost of any postal / courier for the patient and return documents the same way.

ADDITIONAL NOTES

- There is no question of refusing to dispense the prescribed item to patients who sign an exemption claim but do not provide evidence. If patients are unsure whether they are entitled to free prescriptions, you should advise them to pay for their prescriptions and send them a receipt (FP57), in case they want to claim a refund later.
- You will not be held responsible if patients do not provide evidence, or if they provide evidence which is false. If you are in any doubt as to whether the evidence is genuine or appropriate, you should mark the 'Evidence not seen' box on the back of the prescription form with an 'X'.
- You are in no way responsible for the accuracy of the patient's declaration; this remains the responsibility of the patient.

6.12 NHS Business Services Authority Guidance

The NHSBSA provides the following guidance to those involved in the dispensing process [adjusted to reflect distance selling pharmacy Regulations). All contact with patients will be via non face-to-face methods.

- DO
  - encourage your patients to check that they are entitled before claiming free prescriptions. A patient booklet and other resources are available at: www.nhsbsa.nhs.uk/freeprescriptions
  - make sure patients are certain that they are entitled before they complete the declaration on the prescription form. If they are not sure, ask them to pay, issue an FP57 receipt and explain that if they can later confirm that they are entitled, they can claim a refund within three months.
  - ask to see evidence of patients' entitlement and check the expiry date on any certificates you're sent. If a patient can't provide proof, mark the 'Evidence not seen' box on the prescription and remind them that their entitlement could be checked at a later date.
  - explain to patients with qualifying long term medical conditions, pregnant women and those who have had babies in the last 12 months that they must have a valid medical or maternity exemption certificate to be entitled to free prescriptions. To apply for a certificate, they will need to contact their GP, midwife or health visitor.
  - remember that patients who currently pay for their prescriptions may benefit from buying a prescription prepayment certificate or applying for the NHS Low Income Scheme. Visit www.nhsbsa.nhs.uk/healthcosts for more information.
- Don't:
  - make assumptions. Remember that not all benefits entitle patients to free prescription and patients with long term medical conditions like diabetes or epilepsy may not have medical exemption certificates. Even if you have seen a patient's exemption certificate before, it may have expired since then.
  - hurry the patient (or their representative). Give them time to read the declaration on the prescription form and information materials.
  - forget that if a patient makes an incorrect claim, intentionally or otherwise, they could have to pay a penalty charge of up to £100 - as well as the original prescription charge(s). An additional charge of up to £50 may apply if they don't pay on time.
  - turn a blind eye. If you suspect that a patient is fraudulently claiming free NHS prescriptions, visit www.reportnhsfraud.nhs.uk or call the NHS Fraud and Corruption Reporting Line.

6.13 Coronavirus and influenza vaccinations and immunisations

The Pharmacy will not administer medicinal products to patients, but it should be noted that - No charge is payable in respect of the supply or administration to an eligible person of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus whether or not the medicinal product is supplied or administered to that person in accordance with such a patient group direction or protocol.

The pharmacy should check the current eligible persons list for up to date guidance.

6.14 Paid NHS Prescription

- Check the prescription to confirm how many charges are due.
- Check to see if any fees have been paid and if so, was the correct amount paid?
- Contact the patient to arrange payment using the secure payments system using the "customer not present" option.
- If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system.
- The reverse of the prescription should be fully completed.
- If an item is available and cheaper to buy consult the pharmacist.

7. Pharmaceutical & Legal Assessment

7.1 Objective

All prescriptions or orders need to be valid and clinically appropriate for the patient. They must:

- Be safe and appropriate.
- Be Legally valid, allowed on that particular prescription type and not blacklisted.
- Be for licensed indications and dosages with the Prescriber contacted for out of licence use.
- Have all interventions recorded.

7.2 Known Risks

- Poor handwriting on handwritten prescriptions.
- Similar names of medicines.
- Interactions or errors that are not identified.
- New or unfamiliar drugs

7.3 Scope

This SOP provides guidance for the pharmaceutical assessment of all NHS prescriptions, Private Prescriptions and sale of non-prescription medicines. For Controlled Drugs prescriptions and sales of non-prescription medicines, the specific SOP relating to that topic should be referred to as well.

7.4 Responsibility

Dispensers, Technicians, Pharmacists and Responsible Pharmacist. Only those members of the pharmacy team who have been considered competent and have appropriate training can carry out this procedure.

7.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

If as a result of the review any changes to the SOP are deemed necessary, these must be approved by the Superintendent Pharmacist.

7.6 Process

7.7 Pharmacist Checks

Where appropriate you may need to contact the patient or carer to gain further information to help assess the appropriateness of treatment, e.g., finding out the weight of a child for calculating the recommended dosage for children's medicines. The list below provides a guide of the key points to pay attention to when the Pharmacist performs the pharmaceutical check.

- Age of patient.
- Gender of patient.
- Weight of the patient
- Whether the patient is pregnant or breastfeeding.
- The relevant clinical condition.

- Patient Medication Record (PMR) notes e.g., Allergies.
- Interactions with other drugs, foods, supplements or disease states
- Dose and dose changes.
- Strength and strength changes.
- Formulation.
- Route of administration.
- Contra-indications.
- New medicines.
- Quantity and interval prescribed or purchasing.
- Monitoring requirements.
- Whether Medication is appropriate for the patient.
- Consideration of any adjustments required under the Equality Act 2010

Where a prescription is not appropriate in your professional judgement, take the appropriate steps to ensure you consider all your options before coming to a decision.

- Is there guidance available for out of licence use?
- Consequences to the patient of not supplying.
- Consequences of supplying.
- Acting in the patient's best interests of care.
- Reference to reference books and data sheets.
- Discuss with the prescriber.
- Contact the patient to gain further information over the phone.

Clinical interventions must be recorded in the 'Interventions and Referrals section of the patient notes. Record as much information as you feel relevant, as referring back to it at a later date may prove useful. Also make a note in the patient's PMR. Refer to SOP 'Intervention and Problem Solving' for further guidance.

The list below provides a guide of the key points to pay attention to when the Pharmacist performs the Legal check. Where appropriate you may need to contact the patient, prescriber or carers to gain further information.

- Has the reverse of the prescription been completed?
- Is the prescription legally valid?
- Is the prescription genuine?
- Are all the patient details complete?
- Is the medication reimbursable by the NHS?

7.8 Summary Care Record Access

If appropriate, access the patient's Summary Care Record to evaluate the prescription received against the information contained within the record.

7.9 Items Requiring Measuring and Fitting

Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)

8. Interventions and Problem Solving

8.1 Objectives

This SOP is designed to ensure that any interventions that are identified in the Pharmaceutical & Legal assessment SOP are dealt with promptly, professionally and appropriately. Always be aware that:

- Patient safety must always be the priority.
- The nature of the pharmacy as a Distance Selling Pharmacy means that it is not always possible to provide the same services as normal retail pharmacies.
- Customer confidence and good patient relationships should always be maintained.
- Good working relationships with other health care professionals should always be maintained.

8.2 Scope

This SOP covers the events that may occur during the dispensing process.

8.3 Responsibility

Pharmacist and Responsible Pharmacist and all other members of staff

8.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

8.5 Process for Prescription Issues

- **Issues re prescriptions must always be referred to the RP.**
- **Ensure you start by checking that you have contact details for the patient.**
- When contacting the prescriber, try to speak with them, but if they are unavailable then consider speaking with an alternative prescriber from that practice if appropriate.
- Record the details of the intervention in the 'Intervention & Referrals' book, and also make a note in the PMR.
- If you can resolve your query by speaking with the patient over the phone and it is a clinically significant intervention, then record this in the 'Interventions & Referrals' book and make a note in the PMR.
- If a decision has been made not to dispense, then telephone the patient to advise the patient as to the reason and refer them to the prescriber. You should not in any way undermine the trust the patient has in the prescribing Doctor. The intervention should be logged in the 'Interventions and Referral' book.
- If the prescription has no other items on the prescription, return the prescription back to the prescriber with the intervention details attached.
- If the prescription contains other items, then endorse the item that cannot be dispensed as N/D (Not dispensed). Proceed to send a copy of the intervention report to the prescribing Doctor if appropriate.
- If you are working alongside an ACT, attach a note to the prescription of the outcome of the intervention and stamp and sign the prescription in the usual way to confirm a clinical assessment has been performed.

8.6 Matters Relating to Distance Selling Queries

- This pharmacy operates under the Regulations and Terms of Service applicable to distance selling pharmacies. Where any patient requests the provision of an essential service in a face-to-face manner at the premises (which includes in the vicinity of the premises) then this request must be refused.

- A refusal to provide a service that a patient believes they are entitled to receive may surprise patients. It is important to explain to patients that this type of pharmacy is not permitted to provide essential services in a face-to-face manner.

- Do not use phrases such as "essential services" when speaking to patients as this will be confusing. Instead, discuss the specific service that is being requested and explain why it cannot be provided. You may also provide a copy of our Information Leaflet which also provides an explanation of the rules that apply to the pharmacy.

8.7 Patient Queries and Issues

- Ensure you have contact details for the patient.
- Refer the query to the RP.
- If you need to contact a prescriber, then ensure that all relevant information is available before you make contact.
- Keep the patient informed of what you are doing. People normally don't mind waiting for answers if they are being kept informed.
- Discuss the query with the patient.
- Make sure you understand what the patient's position is – i.e., Do you understand their query properly? Repeat the query to the patient to ensure you have the correct understanding but ensure that you don't come across as patronising. Tell the patient that you want to repeat the query in order to ensure that you have understood it properly.
- If you can reach agreement on the appropriate action, then record the agreed action and ensure it is carried out and that all relevant staff are aware of what has been agreed.
- Consider leaving appropriate notes if another RP might be involved in the query at any stage.

8.8 Serious Shortage Protocols

(see PSNC website for further details)

What are SSPs?

Legislation has been passed that will allow for an emergency measure called the Serious Shortage Protocol (SSP) to be put in place to help manage supply if there is a serious shortage of one or more medicines.

The intention is that an SSP will be issued only if a medicine has been judged by the Minister to be in serious short supply. The SSP will set out a clear protocol for community pharmacists to follow if they are unable to source that medicine for patients who have been prescribed it. The protocol will say what other prescription medicines could be dispensed, without the pharmacist needing to go back to the prescriber. For example, pharmacists might be able to:

• Dispense a reduced quantity of medicine.

- Dispense an alternative dosage form.
- Dispense a therapeutic equivalent; or
- Dispense a generic equivalent.

The SSP will specify exactly what alternative quantity, or pharmaceutical form, or strength, or therapeutic equivalent or generic equivalent could be supplied by the pharmacist and under what circumstances.

It is important to understand that an SSP will only be introduced for a medicine if there is judged to be a serious shortage of that medicine. The SSP will only apply to that specific medicine and it will set out clearly what alternatives, for example, a different formulation (e.g., capsules rather than tablets,) pharmacists can dispense. GPs will be notified when an SSP has been put in place so that prescribers will know what adjustments may be being made to their patients' medicines.

The introduction of SSPs does not mean that pharmacists will be empowered to make changes to patients prescribed medicines more widely. Each SSP will apply to a specific medicine, with specific alternatives allowed to be dispensed within a specific time period.

NOTE

- You must follow the protocol in all cases.
- You should notify the provider of primary medical services on whose patient list the patient is of the supply in accordance with the SSP instead of in accordance with the prescription form or repeatable prescription.
- the requirements to act with reasonable promptness in are to be read as requirements to act "within a reasonable timescale". What is reasonable will be judged on the individual circumstances.
- Pharmacists must refuse to supply against the original prescription if a serious shortage protocol is in effect and alternative provision has already taken place.
- The RP must use their professional judgement to decide whether it is "reasonable and appropriate" to supply in accordance with the protocol, instead of the original prescription.

9. Selection, Labelling and Assembly

9.1 Objectives

The aim of this SOP is to ensure:

- Safe working systems
- Accurate selection, labelling and assembly of products.
- That the prescribed product is selected from the shelf (dispensing from the prescription and not from the labels).
- The correct quantity is dispensed.
- The PIL is included with the medicine.
- The product has enough shelf life when in use by the patient.
- The packaging is appropriate for the contents.
- The label is placed on the correct product.
- Consideration is given to the Equality Act.

9.2 Risks

- Assembling medication from the labels, not from the prescription.
- Label print may be too small for patient to read.
- Similar medication names or packaging.
- Split boxes have not been marked.
- Incorrect product selection.
- Not enough shelf life on the product.
- If the product has not been stored correctly so the quality is compromised.
- Incorrectly labelled boxes.

REMEMBER: MANY DISPENSING ERRORS ARE CAUSED BY PRODUCTS WITH SIMILAR NAMES BEING INCORRECTLY CHOSEN FROM THE SHELF!

9.3 Scope

This SOP deals with the selection labelling and assembly of all prescriptions and non-prescription medicines.

9.4 Responsibility

Dispensers, Technicians and pharmacists.

9.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate. If as a result of the review any changes to the SOP are deemed necessary, these must be approved by the Superintendent.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

9.6 Process

9.7 Prescription/Non-Prescription Order Selection

- The prescription/online order should be referred to before and during the selection of the product.
- Read the prescription, NOT the labels when selecting products.
- Products should be selected from the top / front, as stock rotation would mean that newer stock is placed at the bottom / back.
- Check the product has enough shelf life on it for the usage period.
- The prescription must be signed and dated.
- Check if the 'days of treatment' box has been ticked.
- Contact the patient if you know there is a stock shortage, or the item is a special order. Advise the patient of the anticipated date by when the prescription can be fulfilled.
- Check the patient has enough medication to last the duration of treatment.

9.8 Prescription Labelling

If the bar code scanner is used, then many of the fields below will be populated by the PMR system. You should still check the details to ensure that they are correct.

- Select the correct prescription type from the PMR.
- Check the prescription for:
  - Patient name, address and DOB. Double check before selecting a patient from the list.
  - The Prescribers signature.
  - Check the reverse of the prescription has been completed appropriately.
  - Any anomalies or missing information or notes or added information.
- Amend any details like change of name or address as appropriate.
- Perform a thorough search for patients not listed to avoid duplicate records being generated.
- If the patient is not listed, create a new patient record.
- Enter the prescriber details.
- Check the notes for any allergies or information to take into consideration.
- Check PMR notes for any reference to a disability or requirement for alternate methods of dispensing, e.g., MDS or large type labels.
- Enter the prescriptions items in the order that they appear on the prescription.
- Add a note to the prescription to advise the Pharmacist of any changes to treatment, dose, strength etc.
- Check the BNF statutory and cautionary warnings appear on the label.
- Add a note to the prescription to advise the Pharmacist of any drug alerts or interactions.
- Pay attention to any notes about allergies, brand preferences etc. Add these notes if they appear on the prescription or order message.
- Review the prescription summary screen and order stock as appropriate.
- Generate labels.
- Endorse the prescription and then stamp with the Pharmacy address stamp.
- Place the generated labels and prescription in the appropriate coloured basket with the selected stock, taking care to select with reference to the prescription and not the labels.

9.9 Prescription Assembly

- Select the prescription for assembly.
- Ensure you have a clear workspace in which to assemble items.
- Read the prescription and check the patient and medication details correspond.
- Ensure the medication remains in date for the duration of treatment.
- Calculate/measure/count the quantity required.

- If you have sufficient stock, place the selected items in the relevant coloured dispensing baskets with the prescriptions.
- Select one item at a time.
- Be alert to similar packaging used by generic manufacturers. These can be highlighted using Caution Stickers.
- Be aware of any medication that is brand specific to the patient type or condition.
- Check the stock is in good condition.

9.10 Falsified Medicines Directive (as appropriate)

From 9th February 2019, market authorisation holders were required to add safety features on all new packs of prescription medicines placed on the market in Europe:

- a unique identifier (UI) in the form of a 2D data matrix (barcode) which can be scanned at various points along the supply chain to determine its authenticity; and
- an anti-tamper device (ATD).

The Pharmacy will apply any new regulation or guidance introduced by the UK to combat the use of fake medicines as this directive no longer applies in England.

9.11 Split Packs

- If you need to split packs, use a suitable container to repack the medication in:
  - Ensuring that any split packs already present are used up first and then using an un-split pack to make the remaining count volume unless they are from a different manufacturer and appear different as this may confuse the patient.
  - Ensure that the blisters in the pharmacy contain the expiry date and the batch number and are kept in the original pack.
  - Mark all split packs with 'X' using permanent marker on each panel of the pack.

9.12 Liquids

- Leave the stock bottle visible on the draining board if too large or with the basket to allow the Pharmacist / Technician to check against.
- Take time to measure the liquid volume taking care the line of the meniscus is parallel with the volume required.
- When mixing antibiotics etc. follow the manufacturer's instructions to prepare the medication.
- Write the date of opening on the bulk liquid bottle and on its carton.
- A 5ml spoon, oral syringe or a liquid measure should be provided as appropriate. Check the patient age contact the patient or their representative if in doubt about which to provide.

9.13 Bulk Packs

- Use a tablet counter to count out the required quantity of medication. Do not handle medication directly - use latex gloves or tweezers. Leave the bulk pack with the prescription and transfer the medication to a clean tablet bottle.
- If bulk packs are split this should be indicated by marking the pack with an 'X' with ink/marker pen. The mark must be easily seen by any future user of the pack. Mark the ends of the box to assist with identifying the pack as "split".
- Child resistant lids should be used unless it is not appropriate to do so and approved by the RP.
- Make a note on the prescription and PMR notes if the patient requests not to receive child resistant containers or if they have difficulty opening the container.

9.14 Cytotoxics

- Cytotoxics must only be counted using a triangle especially for that purpose.
- Wash the triangle after each use.
- Ensure child resistant closures are used where appropriate.
- Ensure cytotoxics are not dealt with by pregnant staff.

9.15 Valproate Medicines and Females of Childbearing Age

- Valproate medicines must not be prescribed to women or girls of childbearing potential unless they are on the pregnancy prevention programme (PPP).
- All women and girls who are prescribed valproate should contact their GP and arrange to have their treatment reviewed.

9.16 Dispensed by checks

- Ensure that a patient information leaflet (PIL) is supplied. If you do not have a PIL you should download and print one.
- Consider what additional information can be provided to the patient to ensure that they understand how to take their medicines properly and how to get the most from their medicines.
- Attach labels to medicines on an appropriate area.
- Flag labels appropriately for small containers or items to ensure all the relevant information is present for the patient to read and for the pharmacist/ACT to check.
- Refer to the prescription again to check each label on each item corresponds and is correct.
- Mark the 'Dispensed By' box with your initials to indicate the dispensed medication has been checked by the dispensing person.
- Place the basket in the designated prescription checking area.
- Ensure FMD codes are present for later scanning out process.

9.17 Additional Procedures Re Insulin

When a prescription for insulin products is received the pharmacy must check if the patient has an 'Insulin Passport' to record the patient's current insulin products and if not then supply one.

When prescriptions of insulin are prescribed, dispensed or administered, healthcare professionals should cross-reference available information to confirm the correct identity of insulin. Where there is a discrepancy between the Insulin Passport, a patient's notes or current understanding of insulin therapy, it should be reconciled and the information in the Insulin Passport updated.

9.18 Endorse/Code the Prescription

- The electronic endorser must be used for all endorsing unless the RP indicates otherwise for any reason.

10. EPS Nomination and Information[1]

Our access to the EPS system is provided and maintained by our IT supplier and we have signed up to the Priority Services Register (which provides priority access to electricity, water and gas supplies) in order to ensure that it is constant and reliable. In the event of any system outage refer immediately to the RP so that the system supplier can be contacted.

10.1 Objectives

- To ensure that patients are given sufficient information regarding EPS nomination to properly inform their decision.
- To ensure that information regarding nomination is delivered in a consistent and impartial manner in order that no patient or contractor is disadvantaged in any way.
- To ensure that nominations are captured, recorded and changed appropriately, accurately and promptly.

10.2 Scope

- This procedure covers the capture, recording and changing of EPS nominations.

10.3 Training Requirements

- All pharmacy colleagues must have completed this SOP and relevant training with the RP before being able to set an electronic patient Nomination.
- All pharmacy colleagues must be confident how to explain to patients/appropriate representatives about the EPS generally (see leaflet that can be provided to patients) and the nomination process.
- The pharmacist on duty is responsible for the supply of any medicines to a patient.

10.4 Which patients are suitable for Nomination?

- Patients receiving regular medication
- Patients who have their medicine delivered from the same pharmacy.
- Patients wishing to use our Repeat Prescription Service.

10.5 Which patients are less suitable for Nomination?

- Patient who receives prescription infrequently.
- Patients who receive their medicines from multiple different pharmacies.
- Patients who work away or travel regularly.

10.6 Process

10.7 What if there is no access to the EPS?

- Provide the patient with the details of other pharmacies in the relevant area who may be able to dispense the prescription.
- Consider making an urgent supply at the request of a prescriber (see SOP); or
- Contacting the prescriber and ask for the urgent provision of a non-electronic prescription form.

[1] EPS information and procedures are tailored from PSNC recommendations

- When considering requesting a non-electronic prescription check with the patient first to ensure that the timescales involved are acceptable to them bearing in mind that the medication cannot be dispatched until the original prescription is received for the final check.

10.8 Capturing the nomination

Nomination forms are available on the website. If a patient requests information about nominating a dispenser or the EPS service in general give them the following information:

- EPS involves the electronic transmission of prescriptions safely and securely.
- any dispensing contractor operating EPS can be nominated.
- patients are not restricted to nominating a dispensing contractor located close to their GP practice.
- where patients use their nominated dispensing contractor, their prescription will be sent automatically to that dispensing contractor.
- if the patient chooses not to use their nominated dispenser for a particular prescription, they must make that clear at the time of requesting the prescription.
- patients can change their nominated dispensing contractor at their GP practice or any dispensing contractor at any time. This includes when they are part way through a repeat dispensing cycle, any prescriptions which have not been downloaded before the change of contractor will be accessed by the new nominated contractor.
- The NHS App can also be used to nominate a pharmacy contractor
- patients do not have to receive their prescriptions via the Electronic Prescription Service, however, if it is not used, services associated with it (such as nomination) cannot be used.

10.9 Notes

- The patient will be able to nominate one community pharmacy and one dispensing appliance contractor.
- You may not assume that a patient who has used the pharmacy's repeat prescription service will choose to nominate it. Explicit consent and nomination is required.
- Do not offer the patient any inducement such as (but not limited to) discounts or loyalty points in order to gain the nomination. You must not influence the patient's choice in any way.
- There is no minimum age applicable to nomination. Judgement will be needed to determine if it is appropriate to set a nomination. A nomination can be requested by a representative provided they have the patient's consent.
- Once the patient has made their choice ask them to complete and sign a nomination consent form. This form should be stored securely on the PMR to provide evidence of the patient's selection.
- Remember any nominations that were collected prior to the pharmacy going EPS "live" must be re-confirmed with the patient.
- Find the patient's record using the patient's name, registered address, date of birth and gender or, if available, the NHS number.
- Set the nomination as requested by the patient. Repeat if the patient wants to nominate a pharmacy and an appliance contractor.
- If the pharmacy cannot dispense the prescription due to an inability to access the Electronic Prescription Service then we must still take all reasonable steps to ensure that the medication is provided in a reasonable timeframe, which may include;
    - Signposting to another pharmacy in the same area as the patient (NB check in advance if that pharmacy is able to access the system)
    - Consider "urgent supply"

- Consider asking for a written prescription from the prescriber – but NB ask the patient if that works for them in terms of the time taken for that prescription to reach the pharmacy.

10.10 Changing the nomination

- If a patient requests that a nomination is changed, inform them that outstanding prescriptions not collected by the original nominee will be transferred to the new one.
- If the patient has a repeatable prescription inform them the best time to change the nomination is soon after they have collected the last repeat. If they change before, it is possible the original nominee will already have collected the next repeat.
- To make the change find the patient's record and replace the old nomination with the new one. The patient should complete a nomination request form.
- A repeatable prescription can only be issued electronically where it is being sent to a patient's nominated pharmacy. Patients can choose to change their nominated pharmacy before the expiry of the repeatable prescription. In this case, all outstanding issues which have not been downloaded will be transferred to the new nominated pharmacy. This is different from the paper based repeat dispensing system where all issues must be obtained from the same pharmacy.
- The patient can change their own nomination via the NHS app

10.11 Cancelling the nomination

- By default, prescriptions will go automatically to the nominated dispenser.
- If a patient asks who they have nominated, you must look it up and give them the information even if it is not this pharmacy.
- Nomination can only be removed if customer has given us consent. See the EPS Nomination Withdrawal Form
- If a patient's nomination is changed part way through an electronic repeat dispensing cycle, all prescriptions that have not been downloaded will be transferred to the new nomination. If a nomination is removed part way through an electronic repeat dispensing cycle the patient will need to go back to their GP to obtain a new prescription.

10.12 **Using the nomination**

- By default prescriptions will go automatically to the nominated dispenser. If at any time a patient wishes anything different to happen they must inform the prescriber at the time of requesting the prescription.
- If a patient asks who they have nominated you must look it up and give them the information even if it is not this pharmacy.

10.13 **Time Scale**

- All nomination setting, changing and cancelling requests must be dealt with within one working day of the request being made.

10.14 **Responsibility**

- Any member of staff authorised by the practice and who has an individually registered Smartcard with a User Role Profile that allows access to the Personal demographic Service (PDS) may capture, record and change patient nominations.

10.15 **Review**

This SOP will be reviewed annually and whenever there are any changes in the EPS service. The SOP will also be reviewed following any critical incident.

11. EPS Dispensing Process

11.1 Objective

Safe dispensing of EPS prescriptions.

See Repeat Dispensing SOP for additional details re EPS Repeat Dispensing

11.2 Scope

This SOP describes the procedures which should be followed for the retrieval and dispensing process for Electronic Prescription Service (EPS) Release 2 prescriptions in England.

11.3 Procedure

Accessing EPS - Log on with Smartcard and passcode

To access EPS the user should log on using their Smartcard and passcode.

11.4 Download electronic prescriptions

Patients must have nominated the community pharmacy for their electronic prescriptions to be automatically retrieved or manually pulled down by that pharmacy using the Electronic Prescription Service. The Nominated prescriptions, once generated and electronically signed by the prescriber, are sent to the spine and these can be downloaded by the pharmacy. They can also be downloaded by technicians, dispensing assistants and locums providing they have the correct Role Based Access Control associated to their Smartcard. If the prescription is unable to be located then there could be a number of reasons for this, including the fact that staff training may be required, the prescription may be post-dated or there may be technical issues and these should be investigated.

There are three ways a prescription can be retrieved:

1. Where the prescription is flagged for a nominated pharmacy, that pharmacy can download the prescription at any time. Prescriptions will be automatically downloaded once daily (normally first thing in the morning).
2. If the patient posts their token to the pharmacy, or it is collected on behalf of the patient from the surgery; the barcode on the prescription token may be scanned, in order to 'pull down' the prescription to the pharmacy system, this will be more usual for acute prescriptions.
3. The barcode on the prescription token may be entered manually.

Different situations may occur when a patient sends a prescription token to the nominated pharmacy and the following steps should be followed:

11.5 If a patient posts a prescription token to this pharmacy

The prescription may already have been downloaded, dispensed and awaiting medication delivery, or the barcode on the prescription may need to be scanned and the prescription retrieved from the spine. If the prescription has already been downloaded then when the barcode is scanned, the system will alert the user. The pharmacy may wish to consider if staff should check whether the prescription is bagged up first or whether the token should be scanned first and the system used to locate the prescription.

11.6 If a patient contacts the pharmacy and requests a delivery without a prescription token

- Ensure patient's details are confirmed and checked carefully. (This will be the usual process for repeat prescriptions where the patient has not seen the prescriber).

- Print dispensing token if necessary
  - When a prescription token has not been issued, a dispensing token may be required to be printed in the following situations:
    - To support the clinical check/accuracy checking process.
    - For exemption declaration purposes (all except for age exemptions – under 16 years and over 60 years of age).
    - When a prescription has been downloaded by us, as their nominated pharmacy but we are unable to fulfil it (for example if the item is out of stock) on advising the patient of a stock issue over the phone, the patient may wish to try elsewhere. In this case the prescription is released back to the spine, the patient is advised over the phone that the prescription can be accessed at another EPS Release 2 enabled pharmacy. **The entire prescription must be returned back to the spine and not just the items which are out of stock.**
- The dispensing token must also be sent to the patient when we are unable to fulfil the prescription so it can be presented elsewhere.

11.7 Perform professional clinical check

The pharmacist should perform the clinical check.

Any prescriptions with hand written amendments made by the prescriber will need to be referred back to the prescriber for either a new electronic prescription correctly written, or a non-EPS prescription.

11.7.1 Summary Care Record Access

If appropriate, access the patient's Summary Care Record to evaluate the prescription received against the information contained within the record.

11.8 Produce labels for items on prescription and record exemption status

Once the electronic prescription has been downloaded,

select the items which need dispensing and

print the appropriate labels

If the prescription charge exemption status is known then this should be entered accurately at the time of dispensing.

Check labels to ensure they are appropriate (ie no abbreviations).

A prescription with any additional information recorded in the directions areas of the prescription e.g. preservative free, specific brand etc. will need to be referred back to the prescriber for either a new electronic prescription correctly written, or a non-EPS prescription, in order to ensure correct payment.

Assemble items on prescription in line with the *Selection, Labelling and Assembly SOP.*

11.9 Perform accuracy check

Check against the prescription/dispensing token (not against dispensing labels). The supply of all medicines must be supervised by or carried out by the pharmacist in charge.

11.10 Issue prescription items

The prescription should be bagged in accordance with the "Bagging-Up" SOP and delivered in accordance with the appropriate delivery SOP.

11.11 Record the status of prescription items

To complete the dispensing process, the whole prescription needs to be completed and each item should be marked as '**dispensed**' or '**not dispensed**'.

'Dispensed' indicates the prescription item and quantity has been fully dispensed and delivered to the patient.

'Not dispensed' indicates there is no possibility of the item being dispensed.

There are two intermediate status markers which can be used:

With dispenser – partial: this indicates that part of the prescription item has been dispensed and will be completed when stocks become available.

With dispenser – owing: this indicates none of the prescription item has been dispensed and the item is likely to be issued at a later date.

Endorsements should be added electronically, as appropriate, and ensure that this is done accurately for correct payment from the NHS Prescription Services.

11.12 Send dispense notification to the spine

The exemption status information may need to be updated if this wasn't initially known. The spine should be updated after each dispensing event has taken place (only once the patient has received part or all of their prescription). The dispense notification (DN) must not be sent until the prescription has been completed.

Where the Pharmacy dispenses an electronic prescription or makes an urgent supply without a prescription, the Pharmacy must send the form duly completed by or on behalf of the patient, if one is required under regulation 3(3)(b) or (c), (5C) or (5E) of the Charges Regulations in respect of that prescription (which may be the associated EPS token), to the NHS BSA.

All final checks must be performed by the pharmacist on duty

11.13 Top tips for EPS

- Make sure you get all non-age exempt patient to sign a token – this includes each issue of a repeat dispensing regime.
- Setting up the system to print dispensing tokens with one click speeds up the process of printing tokens and preparing Release 2 prescriptions in the pharmacy considerably.
- Dispensers should find a location to store Prescribing and Dispensing Tokens separately to the FP10s to ensure they can be bundled and sent separately from the FP10s at the end of the month when claiming from the reimbursement agency.

- You can print a prescription or dispensing token for the patient if they ask for a copy whenever required and send it to them by post.

12. Prescription Owings

12.1 Objectives

Customers need to be informed of any stock shortages as soon as possible. They also need to be aware of the options available to them so that they can make an informed decision. Every attempt should be made to satisfy the patient that all efforts are made to obtain stock and rectify the shortage. The process will ensure that all patients will receive an owing slip generated using the PMR for items that contain owings.

12.2 Scope

The process for selection, labelling, and assembly of all prescriptions (NHS and private) except those for oxygen, special orders or monitored dosage systems.

12.3 Responsibility

Dispensers, Technicians, ACT's, Pharmacists and RP.

12.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

12.5 Process

- **Contact the patient/representative** – advise them of the nature of the owing, the estimated time of availability, and/or manufacturing/out of stock issue.
- If the patient does not want to wait for stock to become available then arrange for the prescription to be returned to them or returned to the NHS spine if EPS.
- Order sufficient stock.
- Generate owing labels using PMR and affix to owing slips – mark the owing slips with any relevant information including the patient contact details and 'CD' if it is a controlled drug. Note that owings slips may be provided electronically to patients
- Attach pharmacy and patient copy of owing slip to completed prescription.
- Store prescription and completed medication in the relevant place for owings.
- Stock arrives for prescription – update stock levels.
- Dispense owing and endorse prescription – ensure to dispense the owing following dispensing SOPs and with reference to the prescription.
- Mark owing slip to indicate owing is complete.
- Continue to Bagging Up SOP.

In a situation where it is clinically important that the patient receives part of the owing before the rest of the stock arrives, the following procedure must be followed:

- Attach the pharmacy copy of the owing slip to the prescription.
- Attach the patient copy of the owing slip to the dispensing bag - ensure this contains the estimated date of delivery of the remaining medication and continue to Bagging Up SOP.
- File the prescription in the relevant place for owings.
- When stock arrives follow procedures for owings.

- Remember - If there is likely to be a clinically significant delay in dispensing the medication then refer to the Intervention & Problem Solving SOP for guidance.

12.6 Owings for CDs

All owings for CDs should have 'CD' marked on the owing slip and the customer should be contacted and informed that their prescription must be successfully delivered within 28 days.

Safe custody requirements should always be considered during the dispensing and owing process for CDs.

12.7 Owings that cannot be delivered

If an owing has been unsuccessfully delivered and the Prescription Delivery SOP has been followed then prescription will be stored for a period of 2 months. If it has not been successfully delivered at this point the following procedure should be followed:

- Prescription should be marked as 'not delivered' on PMR.
- Any suitable medication should have the labels removed and be returned to stock – medication is suitable to return to stock if the expiry date and batch number are still visible and the product has an acceptable shelf life.
- Any medication that is not suitable to be returned to stock should be discarded in a DOOP container.
- Prescriptions where no items have been dispensed should be returned to the prescriber, otherwise they should be given to the RP to annotate appropriately.

13. Accuracy Check

13.1 Objectives

This process is to be followed after the proceeding SOPs and before packing any medicines for sending to the patient. This SOP is essential to ensure:

- Accuracy and quality in the proceeding processes.
- Adherence to the Proceeding SOPs.
- Any errors are identified and recorded as near misses.
- The checks of medication, quantity, strength, form, dose, expiry, and PIL are made.
- Ensure the 'dispensed by' checks have been performed.
- Ensure the correct bulk packs have been used.
- Ensure that split packs have been marked and dated in the case of liquids.
- Ensure that the split packs have the right medication inside them, taking care with the strength.
- To ensure that the supply of all medicines is supervised by or carried out by the pharmacist in charge.
- Ensure adjustment required due to disability have been made (Equality Act)

13.2 Risks

- Self-checking by the pharmacist.
- Distractions or interruptions.
- Unfamiliar or new medication, patients, or prescribers.
- Medication/items may be dispensed incorrectly; Similar looking packs may have been dispensed in error due to them being stored incorrectly. Similar sounding names may have been confused and selection of the wrong product may result.
- Medication may be out of date.
- Split packs may have the wrong products inside.
- Split packs may not have been marked and considered full packs.

13.3 Scope

The accuracy check of all NHS and private prescription dispensed, except monitored dosage systems.

13.4 Responsibility

Pharmacists and approved ACT's.

13.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

13.6 Process

REMEMBER: THE ACCURACY CHECK IS IMPORTANT. IT IS NOT JUST ABOUT GLANCING AT A COLLEAGUES WORK. THIS IS THE FINAL CHECKS BEFORE THE MEDICINE GOES TO THE PATIENT. EVEN WHEN THE PHARMACY IS BUSY IT IS IMPORTANT TO MAKE TIME TO CARRY OUT THIS CHECK CAREFULLY

AND WITHOUT INTERRUPTION. THE DISPENSING PROCESS MUST BE CARRIED OUT UNDER THE SUPERVISION OF THE PHARMACIST ON DUTY.

FOR ANY SELF-CHECKING MAKE SURE YOU TAKE A "MENTAL BREAK" BETWEEN DISPENSING AND CHECKING – NOBODY THINKS THEY MAKE MISTAKES!!

- Ensure the dispenser or technician has marked the 'dispensed by' box.
- Check that all the prescriptions in the basket are for the same patient, by checking the name, address and DOB.
- Check the patient name and address on the labels against the prescription(s).
- Ensure the name and address on the bag label, correspond with the details on the prescription.
- Refer to the prescription and check each item in the basket corresponds and is correct. Pay attention to the following details:
- Check whether the patient requires any modification to normal dispensing process due to a disability (eg large type labels)

13.7 Product Checks

- Product name, quantity, strength and form.
- Check multiple packs of the same strength.
- Check the content of all the items against the prescription and carton.
- Take special care with split packs and similar looking packs and brands.
- Visually check the contents of the dispensed medication against the bulk packs of tablets, ensuring split packs have been marked.
- If dispensing liquids, check against the stock bottle/original bottle where relevant, and that the bottle has been marked with the date opened, on the bottle and corresponding carton.
- Check the medication will remain in date during its period of use.
- Check the packs contain the relevant PIL, if they don't, print one off from www.medicines.org.
- Ensure warning cards are included, e.g. Lithium, Warfarin, Steroid and Methotrexate.

13.8 Label Checks

- Check the label against the prescription paying special attention to
  - patients' name,
  - medication name, strength, quantity, form, dosage and
  - any warnings and cautionary information.
- Ensure the label has been placed on the inside pot, unless the size of pack does not allow.
- Ensure that the label has not obscured the product name, strength and form. Feed back to the dispenser on the most appropriate way to place the label. Ensure flagging of labels occurs where necessary.
- Initial the 'checked by' box on the label once the above accuracy checks have been completed.
- Consider if large text labels are required for patients with poor sight (check PMR)

13.9 Prescription Checks

- Ensure the correct endorsements have been recorded on the prescription and make any required changes
- Check the reverse of the prescription has been completed.
- Include spoons, measuring cups, or oral syringe as appropriate.
- If an error has been identified to have occurred in the assembly or labelling stage, refer back to the dispenser/technician involved to correct as soon as possible. Record as a near miss in the 'Near Miss Log'. Ensure reviews of near miss incidents are performed on a regular basis.

- Once you are happy that the *clinical check* and *accuracy check* has been performed on the prescription products, you may then proceed to the *bagging up* process straight away.

14. Emergency Supply and Urgent Supply

Whilst the Distance Selling nature of the pharmacy is such that Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff must be aware of the procedures to be followed in the event of such a request.

14.1 Objectives

In an emergency Pharmacists are able to supply a POM without a prescription to a patient if requested by the following:

- Prescriber (Urgent supply at the request of the prescriber).
- Patient (Emergency supply at the request of the patient).

14.2 Risks

- Emergency request not genuine.
- Prescriber not genuine
- Prescription not fulfilled within 72 hours.
- Change of treatment regime.

14.3 Scope

The following is a list of prescribers that can authorise an emergency supply under certain conditions.

UK registered Prescribers:

- Doctor, Dentist, Supplementary Prescriber, Community Practitioner Nurse Prescriber, Nurse Independent Prescriber, Optometrist Independent Prescriber, Pharmacist Independent Prescriber.

EEA or Swiss registered prescribers:

- Doctor or Dentist.

14.4 Responsibility

Dispensing Assistants, Dispensing Technicians, Accuracy Checking Technicians, Pharmacists.

14.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

14.6 Process

14.7 Urgent supply at the request of a prescriber

The following conditions must apply to the request made by a prescriber:

- **Prescriber**

  The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above. It is likely that, for repeat customers, the details of the prescriber will be known

to pharmacy staff and included on the PMR system. The RP should still carry out appropriate checks on professional registers in order to satisfy themselves that the request is a legitimate one.

- **Emergency**

  The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.

- **Prescription**

  The Prescriber agrees to provide a written prescription within 72 hours.

- **Directions**

  The medication is supplied in accordance with the prescriber's directions.

- **Controlled Drugs**

  An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.

  EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.

- **Records**

  An entry must be made in the POM register on the day of supply with the following details:

  - The date the supply was made.
  - The name, quantity, strength and form of the medicine.
  - The name and address of the prescriber requesting the emergency supply.
  - The name and address of the patient for whom the medication is supplied.
  - The date on the prescription.
  - The date on which the prescription is received in the Pharmacy.
  - The amount charged to the patient, if required.
  - The nature of the emergency (i.e. the reason for request).

In urgent cases, it may be possible for the prescriber to request verbally that an alternative be dispensed on the agreement that a new prescription will be supplied within 72 hours.

14.8 Summary Care Record Access

If appropriate, access the patient's Summary Care Record to evaluate the request received against the information contained within the record.

14.9 Emergency supply at the request of a patient.

The following conditions must apply to the request made by a patient:

- **Interview**
  The Pharmacist must interview the patient. The interview may not be by way of face to face contact and must be by other means, e.g., telephone, Live video.
- **Immediate Need**
  The Pharmacist must be satisfied that there is an immediate need for the medicine and that a prescription cannot be obtained from the prescriber.
- **Previous Treatment**
  The patient has been previously prescribed the medicine by an authorised prescriber. If the patient is requesting a medication which they have not previously been prescribed they must be referred to the appropriate prescriber.

- **Dose**
  The dosage is correct and appropriate for the patient.
- **Controlled Drugs**
  Phenobarbital may be supplied to patients registered with a UK prescriber only for the treatment of epilepsy.
- **Duration of Treatment**
  For Phenobarbital and Schedule 4 and 5 CDs: Maximum quantity that will allow up to 5 days treatment.

- **Other POMs:** Maximum quantity that will allow up to 30 days treatment unless the medicine is:
  - Insulin, ointment/cream or an inhaler for asthma: supply the smallest pack available.
  - Oral Contraceptive: supply a full treatment cycle.
  - Liquid preparation of an antibiotic for oral administration: supply the smallest quantity that will provide a full course of treatment.

- **Records**
  An entry must be made in the POM register on the day of supply and include the following details:
  - The date the supply was made.
  - The name, quantity, strength and form of the medicine.
  - The name and address of the patient for whom the medication is supplied.
  - The amount charged to the patient if required.
  - The nature of the emergency (i.e. the reason for request).
- **Labelling**
  The label for the dispensed medicine must contain the words “Emergency Supply”.

14.10 Faxed Prescriptions and Prescriptions Received in Non-Standard Forms

A faxed prescription does not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A faxed prescription can confirm that at the time of receipt a valid prescription is in existence, however, prescribers should now use other methods (such as scans via secure NHS mail) to send these requests.

Prescriptions send as attachments, even via NHS email are also not legally valid and should be considered in the same manner. These types of prescriptions and faxes are referred to here as “non-standard”

The pharmacy cannot dispense against non-standard prescriptions and instead should use the Emergency Supply procedures if supply is required urgently.

- **Payments for Emergency Supplies at the Request of the Patient**
  Emergency supplies should be priced on the same basis as private prescriptions, subject to the professional judgement of the pharmacist on duty. It is company policy to charge for emergency supplies. However if the patient is able to send a prescription form to cover the item supplied within five working days you may offer a full refund. It is our policy to never refuse treatment only because of an inability to pay and the RP must use their professional judgement to assess each situation that arises.

  As detailed above the patient should be interviewed over the phone. Payment can be processed via the website or over the phone. The pharmacist may wish to consider the following before providing an emergency supply at the request of the patient:

  - You should consider the medical consequences of not supplying.

- You should identify the patient by documentary evidence or personal knowledge.
- You should identify the prescriber who prescribed the medicine on a previous occasion.
- You should ask the patient whether the doctor or dentist has stopped the treatment
- You should ask the patient if any other medicines are being taken at the same time to check drug interactions.
- An emergency supply should not be made if the item requested was prescribed more than six months prior to the request.
- Give less than 30 days' supply if this is appropriate.

Under legislation enacted in November 2008 it is now permissible to make an emergency supply to patients previously prescribed a POM (excluding all Scheduled CDs i.e. 1-5) by an EEA/Swiss registered prescriber (including Dentists). Prescribers from these countries can also request an emergency supply for a patient. In this case the original prescription must be provided to the pharmacy within 72 hours

14.11 Delivery of Urgent and Emergency Supply Items

Given the nature of a request of this type, the Pharmacy should prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are "URGENT" and for any items delivered by courier, the company must be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy must not charge additional fees to the patient even if these are incurred in the delivery process.

Refer to relevant delivery SOP for further information on the delivery process.

15. Supply in Accordance with a PTP

15.1 Objectives

"PTP" means a pandemic treatment protocol, which is a protocol—

(a) relating to the supply of a prescription only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of it being imminently, pandemic; and

(b) approved in accordance with regulation 247 of the Human Medicines Regulations 2012(4) (exemption for supply in the event or anticipation of pandemic disease);".

15.2 Risks

Emergency request not genuine.
Prescriber not genuine

15.3 Responsibility

Dispensing Assistants, Dispensing Technicians, Accuracy Checking Technicians, Pharmacists.

15.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

15.5 Process

The following conditions must apply to the request

- Message received via a secure service approved by NHSCB
- Message must amount to an order for the supply of a drug
- The order must be in accordance with the PTP

In any case where such an order is believed to have been received the order should be referred to the RP.

The RP must check the relevant PTP to ensure compliance with its particular terms.

If a person who is entitled to be supplied with the relevant drug under the protocol requests the drug in accordance with that order then the pharmacy must, with reasonable promptness, provide that drug and follow the delivery process relevant for the class of drug ordered.

The RP should (and if requested to do so by the person being supplied must)

- Provide an estimate of the time the drug will be ready and delivered.
- If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.
- Contact the patient to confirm dispatch of the medication.

In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;

THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE [INSERT NAME] PANDEMIC TREATMENT PROTOCOL

And insert the name of the relevant protocol.

15.6 Refusal to Supply under PTP

The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

(a) The RP reasonably believes it is not a genuine order for the person who requests ,or on whose behalf is requested, the provision of the drug;

(b) providing it would be contrary to the RP's clinical judgement;

(c) The RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying[2] (see footnote re "accompanying") that person; or

(d) the person who requests the provision of the drug, or any persona accompanying[3] (see footnote re "accompanying") that person, commits or threatens to commit a criminal offence.

The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP.

Any refusal to supply must be noted on the patient and / or pharmacy record system.

15.7 Summary Care Record Access

If appropriate, access the patient's Summary Care Record to evaluate the prescription received against the information contained within the record.

[2] As a DS pharmacy patients will not be attending in person and accompanying should be considered in terms of another person who may contact the pharmacy about the patient.
[3] As a DS pharmacy patients will not be attending in person and accompanying should be considered in terms of another person who may contact the pharmacy about the patient.

16. Bagging-Up

16.1 Objectives

This SOP will ensure:

- The correct products are placed in the prescription bag
- The completed prescription bag is stored in the correct location
- Any split packs, bulk packs of medication remaining after the dispensing process are returned to the appropriate area.

This SOP is essential to ensure the correct medication is packed with the correct bag label and corresponding delivery label. It is to ensure that the medicines are stored and then dispatched under the correct conditions for that particular medicine. It also ensures that the patient receives any relevant information in relation to their treatment in the form of the delivery note, owing labels, PIL and help and advice leaflets and any relevant service leaflets that the patient may benefit from.

16.2 Risks

- Wrong bag label placed on wrong bag.
- The contents of the bag mixed with the contents of another patient's bag.
- The original pot/container being bagged as well.
- The contents are not complete and not bagged.
- The additional labels indicating storage requirements have not been used, resulting in chilled items or CD not being stored correctly.
- Multiple bags not being marked appropriately so rendering an "undelivered" status.

16.3 Scope

This SOP covers the procedure for packing and labelling of all NHS and private prescription orders, and all online orders for non-prescription medicines, except monitored dosage systems.

16.4 Responsibility

Dispensing assistants, Dispensers, Technician and Pharmacists.

16.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

16.6 Process

- Ensure that the basket contents have all been checked; indicated by the 'checked by' box being marked.
- Ensure that any bulk packs have been removed and are at no risk of being bagged up as well.
- Ensure that the contents of the basket are labelled for the patient as detailed on the prescription and correspond with the delivery note being placed in the bag.
- Check that the delivery label matches the patient details on the prescription, order voucher and medicine bag.

- Check that FMD codes have been printed properly on the bag
- In the case of non-prescription orders; ensure that the contents of the basket contain the products as per the order and against the corresponding delivery note.
- Ensure that all medicines have been supplied with Patient information leaflets and any relevant advice leaflet in relation to health promotion, whether it is general advice to all patients and/or targeted specific advice based on patient's disease state.
- In the case of owed medication, attach an owing label to the delivery note with an estimation of when the medication will become available.
- Ensure that a return address for the pharmacy is marked onto the package.
- Mark the package with the words 'Urgent Medical supplies' but do not describe exactly the contents of the package.
- Place a 'Private & Confidential' label on the package.
- Label the parcel according to the required storage conditions i.e. 'store in a refrigerator 2-8*C'.

16.7 Choice of Packaging

- Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.
- All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.
- Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.
- DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.
- For postal items, either:
    - At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.
    - For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes**
- Large or any fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.
- Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used.

17. Order Delivery

17.1 Scope

The process for delivery of prescriptions to the patient's chosen address and the provision of information and advice to patients to whom drugs are supplied about the safe keeping of drugs and return of unwanted medicines.

17.2 Objective

This SOP will ensure that:

- Prescriptions are delivered safely and securely
- A robust audit trail is maintained
- Medication is properly delivered
- Patients are aware of missed deliveries and can easily arrange re-delivery.
- Patients receive information on safe keeping and return of unwanted medicines.

17.3 Risks

- Delivery to the wrong person/address.
- Missed deliveries.
- Deliveries of CDs.
- Multiple deliveries of medication.
- Full quantity not supplied.

17.4 Responsibility

Dispensing Assistants, Dispensing Technicians, Accuracy Checking Technicians, Pharmacists, Delivery Drivers.

17.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

17.6 Choice of Delivery Method

For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below).

17.7 Process

17.8 Preparation for delivery

1. **Ensure that prescriptions for delivery are securely bagged and appropriately labelled.**

2. **Complete the Delivery Driver Record Pad with the:**

   - Patient name and address (a bag label can be used) and alternate delivery address if appropriate
   - Any messages for the patient/representative
   - Authorisation has been obtained to deliver to a third party, if appropriate, in writing.

3. **Pack the prescription bag and any other items for delivery securely in the appropriate outer packing.** Ensure that all relevant paperwork and any notes from the pharmacist are included.

4. **Send a confirmation message to the patient via their preferred method of non face to face communication to let them know that their items are ready for delivery and confirm the estimated delivery time.**

17.9 Inclusion of Information on Storage and Return

The pharmacy Terms of Service state that a pharmacy must provide appropriate advice to patients to whom drugs are supplied about the safe keeping of drugs and return of unwanted medicines.

For new patients, written information on safe storage and the returns process should be included with new deliveries. Patients should also be directed to the pages on the pharmacy website that provide details on the safe storage and return of unwanted medicines.

17.10 Transfer to the Delivery Driver

- Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.
- Ensure that any special instructions for the delivery are included with the packaging.
- Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.
- Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.
- Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.
- Ensure the delivery driver is notified of any messages for the patient or representative.
- Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.
- Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended.
- At hand-over to the driver / courier ensure that any current falsified medicines regulation or guidance is followed.

17.11 Delivery of prescription to patient or representative address

- The delivery driver must not enter the patient or representative's home unless invited to do so at the time.
- The patient should be referred to the pharmacist should they have any query about how to use their medication safely and appropriately.

1. **Ask the patient/representative for their name and address.**
2. **Check the patient name and address against the prescription and the bag label.** Patient confidentiality should be maintained at all times, especially if delivering to a representative.
3. **Where appropriate ask the patient or representative to complete the reverse of the prescription.**
4. Hand the medication to the patient or representative.

5. **Ask the patient or representative to sign their details on the delivery sheet**. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.
6. **If necessary, collect any medication returns**. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance.

17.12 Successful delivery

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be stored safely for a minimum of 3 months.

17.13 Unsuccessful Delivery

1. If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.
2. The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.
3. The pharmacy should follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.
4. **DO NOT:**
    - Post the medication through the letter/post box.
    - Leave the medication in the porch or any other out building.
    - Leave the medication at an unauthorised address.

17.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)

1. Follow preparation for delivery process. The pharmacist should contact any patients for whom there are relevant messages or counselling required.
2. Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.
3. Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.
4. Ensure a return address is printed clearly on the outer packaging.
5. Confirm details of all prescriptions to be delivered.
6. Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.
7. Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.
8. Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.
9. All deliveries will require a signature from the patient to confirm receipt of their prescription.

17.15 Unsuccessful Delivery via Royal Mail

In the event of an unsuccessful delivery, Royal Mail will leave a 'Sorry We Missed You' card, stating the date and time of the attempted delivery. The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or email.

17.16 Cold chain delivery via courier

Explanatory Notes:

See "Bagging Up" SOP for cold chain packaging guidance

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach.

CURRENT (NOMINATED) COLD CHAIN COURIER COMPANY IS……

ALTERNATE COLD CHAIN PROVIDER…….

Staff should confirm with the RP if wishing to use a courier company other than the NOMINATED courier above.

1. Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

2. Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

3. A delivery should be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),

4. Select a delivery maintaining 2– 8°C unless the item requires shipping at a different temperature.

5. The cold chain item should be kept in the fridge until the courier arrives to accept the delivery.

6. Confirm with the courier that the delivery will be maintained at the booked temperature range.

7. Confirm details of all prescriptions to be delivered.

8. The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number.

9. Make a note of all Tracking numbers for prescriptions being delivered by the courier on Delivery Log sheet.

10. Ensure courier signs Delivery Log sheet for all prescriptions being accepted for delivery.

11. Remove items from the DELIVERY FRIDGE and match against the delivery log and place a copy of the barcode sticker on the packaging.

12. At hand-over to courier scan the aggregated FMD code (the system will disaggregate the unique identifiers and forward them to the NMVS for decommissioning)

13. Give all fridge line deliveries to the courier.

14. Store Delivery Log sheet for a minimum of 3 months from dispatch date.

15. Contact the patient and dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website.

16. All deliveries will require a signature from the patient to confirm receipt of their prescription.

17.17 Unsuccessful cold chain delivery via courier

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery.

17.18 Breach of Integrity of Cold Chain

The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.

The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock.

18. Safe and Effective Storage of Medicine

18.1 Objectives

- Understand how to maintain an effective cold chain for chilled items.
- Evidence that pharmaceuticals are continuously stored within the manufacturer's product license specifications.
- Ensure that refrigerators are maintained and operated correctly to ensure that the temperature is within the recommended guidelines (between 2°C and 8°C).
- Correct procedures are followed if there is a breach of the cold chain storage conditions.
- Stock is properly rotated

18.2 Risks

- Incorrect storage of medicines which require cold storage.
- Use of domestic refrigerators is a risk as they do not maintain and equal temperature within the appliance.
- There is a risk of the refrigerator failing to maintain within the required temperature range, due to power failure or a refrigerator breakdown.
- If the refrigerator temperature is not being monitored and recorded daily this results in a failure to identify any faults with the refrigerator or breach of cold chain.
- Dispensing or supplying short dated or expired medication.

18.3 Scope

Receiving and storage of ambient medicines including Sch 2 & 3 CD's and the recording of the Pharmacy fridge temperature.

18.4 Responsibility

Dispensers, Technicians, Pharmacists and Responsible Pharmacist.

18.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

18.6 Process

Authorised Dispensary Staff

Before signing for receipt of medicinal goods:

- Check that the number of outer packages which you are signing for matches the delivery documentation, and that the outer packages are for your pharmacy.
- Check that refrigerator packages are accounted for.
- Where a discrepancy arises, amend the documentation before signing.
- Containers which were not ordered should not be received and should be taken back by the wholesaler.

Pharmacists

Also refer to 'Controlled Drugs: Receipt & Storage'. Before signing for receipt of schedule 2 or 3 controlled drugs (CD)'s:

- Open the outer packaging (usually an envelope or blue bag) to view the items.
- Confirm the name, quantity, strength, formulation and expiry date of the product matches the documentation you are signing for.
- Check that the manufacturer's tamper-evident seal is intact.
- If you receive Items that were not ordered or where the manufacturer's tamper-evident seal is not intact, the wholesaler should be contacted immediately to seek further guidance on their returns policy. If they advise not to accept then do not sign for the delivery and hand it back to the delivery driver.
- Where a discrepancy arises, amend the documentation before signing where necessary.
- Make an entry into the CD register for any schedule 2 CD received immediately (or in exceptional circumstances, by the next day).
- Check the running balance is correct for the specific CD.
- Store schedule 2 CDs in the CD cupboard making sure that products with the longest expiry are placed behind the same product with a shorter expiry.
- Store schedule 3 controlled drugs (unless exempted) in the controlled drugs cupboard.
- Lock the cupboard and secure the CD key.

18.7 Checking the order and putting away the stock

- Fridge items should be dealt with as a priority.
- Work in a clear and uncluttered space.
- Place the contents of a medicines container onto the work space.
    - Group multiple packs of the same medicine together.
    - Check each medicine against the invoice.
    - Check the expiry date of medicine received.
    - Isolate medicines from the order which have been ordered in error.
    - Isolate medicines from the order which are short-dated or expired.
    - Isolate medicines which are leaking or damaged.
    - Make a note of items ordered which are missing from the order.
    - Keep invoices for 6 years.
    - Store fridge items in the fridge, making sure those products with the longest expiry are placed behind the same product with a shorter expiry.
    - Do not place items directly against the cooling plate to avoid freezing the product.
    - Where possible allow a finger width between each group of products.
- Store all other items in the appropriate area making sure that products with the longest expiry are placed behind the same product with a shorter expiry.
- Repeat until all containers have been emptied.

18.8 Returning medicines ordered in error

- Locate and complete the applicable returns documentation.
- Obtain prior authorisation for the return of the medicines if applicable.
- Return the medicines to the supplier delivery driver when it is next practicable to do so.
- Ensure that the delivery driver signs the applicable documentation and a copy is retained in the pharmacy.
- When the credit note is received indicate this on the returns documentation.

18.9 Dealing with missing items

- Locate and complete the applicable missing medicines documentation.
- Ensure that the supplier delivery driver signs the applicable documentation and a copy is retained in the pharmacy.
- Re-order the missing medicines where necessary.
- When the credit note is received indicate this on the missing medicines documentation.

18.10 Date checking & stock rotation

- Using the current date checking matrix:
  - Record details on the quarterly date checking matrix.
  - Fill in the applicable year.
  - Fill in the applicable quarter.
  - Fill in the schedule with the week commencing (w/c) dates.
  - Amend the areas of the pharmacy to be checked according to the requirements within the pharmacy remembering that all medicines must be covered by the date checking matrix.
  - Include over-the-counter medicines within the date checking matrix.
- All pharmacy stock must be date checked every 3 months according to the schedule.
- Remove all the pharmacy stock from the area which is to be date checked.
- Wipe and clean the date check area.
- Check the expiry date for the products.
- Isolate any pharmacy stock with an expiry of less than 1 month. Also isolate any stock which would expire before it could be fully used if it were dispensed now – for example where the pack is for a quantity for more than a month's supply such as a triple pack.
  - Make a record of this stock for stock check purposes and write off the stock.
  - Dispose of this stock following the 'Safe & Effective Disposal of Medicines' SOP.
  - For any other pharmacy stock which will expire within the next 4 months, write down details and batch numbers– Record the details in the Date expiry table for the appropriate month.
- Use a small sticky coloured label to "flag" the short dated stock.
- Return remaining stock to the shelf making sure that stock with the shortest expiry date is placed where it will be used first.
- Complete the date checking matrix by signing to declare that the pharmacy stock has been date checked for that area.
- On a monthly basis check the relevant monthly expiry table for products expiring in that month.
  - Locate and remove any products which have not been dispensed in the interim.
  - Make a record of this stock for stock check purposes and write off the stock.
  - Dispose of this stock following the 'Safe & Effective Disposal of Medicines' SOP.

18.11 Temperature and environment

- Medicines must be stored according to individual manufacturers' requirements and away from direct sunlight, heat source or moisture.
  - Items requiring storage between 2-8°C must be stored in the refrigerator.
  - Items requiring storage in a "cool dry place" or below 15°C must be stored under these conditions or otherwise in a refrigerator.
  - Where possible products should be stored in the body of the fridge, not on the floor, drawers, in the door, or near to a freezer compartment. This is especially important for

high-risk cold chain products such as insulin and vaccines. The fridge should not be overloaded or packed too tightly to allow the flow of cold air.

- Food and drink must not be stored in the pharmacy fridge.
- Where items have been stored in adverse conditions then the stability of the product must be considered in light of the duration of time that the medicine was exposed to adverse temperatures.
- Contacting the manufacturer for further information may be necessary.
- Medicines considered to be unstable must be written off and disposed of.

- **On a daily basis:**

  - Check the fridge temperature and record the maximum and minimum temperature into the 'Fridge Temperature Record Chart'.
  - 'Fridge Temperature Record Charts' should be retained for the life of any product which has been stored within. In practice this means that the records may need to be kept for years.
  - Reset the thermometer following the manufacturer's instruction.
  - Where the temperature falls outside of the 2-8°C range then assess the maximum length of time that the medicines have been exposed to temperatures outside of the recommended range.
  - Record any findings and actions taken on the record chart along with details of who performed the actions.

- **Cold chain breaches**

  It is the professional judgement of the RP on duty to determine if the cold chain has been breached sufficiently to make supply of the medications inappropriate or unsafe.

  The length of time that the product has been out with the guideline temperature should be a factor in consideration.

  Contact the manufacturers of each medicine for guidance on the stability of the medicine, as they may not be suitable for supply to patients. Supply of a medicine that has not been stored in accordance with the manufacturer's storage requirements will be outside of the product licence for the medicine. The Responsible Pharmacist must use their professional judgement to determine if such a supply is appropriate.

  - Medicines considered to be unstable must be written off and disposed of following SOP 'Safe & Effective Disposal of Medicines'.

19. Controlled Drugs: Receipt and Storage

19.1 Objective

The safe and secure receipt and storage of controlled drugs in the Pharmacy.

19.2 Scope

This SOP, therefore, covers only those CDs which are in Schedules 2, 3, 4 and 5, with the exception of Sativex spray.

19.3 Responsibility

Dispensers, Technicians, Pharmacists and Responsible Pharmacist.

19.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure

19.5 Process

19.6 Accepting schedule 2 and 3 CD's in the Pharmacy

- The RP must accept Schedule 2 and 3 CDs.
- All stock received should be physically checked. The stock must be in good condition and tamper seals must be intact.
- The expiry date must be checked. Different types of stock will have different expiry times, but you should not accept any stock that has less than 12 months unexpired shelf life unless it is for a specific prescription and will be dispensed and used by the patient prior to expiry.
- Check that the correct item has been ordered and delivered.
- Check the quantity ordered matches the quantity delivered and the quantity on the invoice.
- If all details are correct then sign the delivery note and return this to the driver.
- If the delivery is incorrect, damaged or short dated refer to section below '*Dealing with an incorrect/damaged delivery*.'
- Enter all relevant CD stock into the CD register as soon as possible (on the same day)
    - Include the invoice number in the entry in the CD register — this is useful for tracking any errors in entry or discrepancies.
    - Carry out a stock check and verify the balance in the CD cabinet; enter the new balance (the sum of the existing stock plus the new stock)
    - If there is a discrepancy refer to SOP 'Controlled Drugs Stock balance checks'.
- Items subject to Safe Custody Regulations must be stored in the CD cabinet immediately — this includes ALL Schedule 2 CDs and certain Schedule 3 CDs. Refer to the 'Medicines, Ethics & Practice Guide' for a comprehensive list of CD schedules.

19.7 Dealing with an incorrect /damaged delivery

- If the order contains incorrect stock, stock with a broken tamper-evident seal, damaged or short-dated stock, contact the wholesaler immediately before accepting the delivery from the driver and confirm the returns policy for incorrect/damaged stock.

19.8 Delivery

- Follow the guidance issued by the wholesaler regarding the returns procedure and/or claims procedure if damaged or incorrect stock is received, completing any necessary paperwork.
- If the damaged stock involves a broken bottle of a CD liquid (for example Oxycodone solution):
  - Refer to section “Damaged stock that cannot be returned to the wholesaler”.
- If the delivery driver is unable to return the stock immediately and it has to be accepted by the pharmacy, enter any stock into the CD register if there is a legal requirement to do so.
  - Annotate the register using an asterisk (*) and explanatory footnote to state that the item is awaiting return to the wholesaler and include a reason
  - Record full details in the pharmacy interventions book.
- Store any stock that is to be returned to the wholesaler and is subject to the safe custody requirements in the CD cabinet
  - Separate from normal dispensing stock
  - Place in a bag and clearly label to show that it is awaiting return to the wholesaler
- Other CD stock, not requiring storage in the CD cabinet, and awaiting return to the wholesaler should be stored on the Returns Shelf (Quarantined area marked with red tape)
- Check whether the damaged/incorrect stock needs to be re-ordered urgently — in order to fill a prescription, for example.
- Re-order replacement stock and contact the patient, if necessary, to advise them of any likely delay in filling their prescription.
- Manually update any stock levels held on the pharmacy automatic ordering system to reflect the correct stock levels, if appropriate.

19.9 Collection of incorrect /damaged stock by the wholesaler

The pharmacist must supervise this process

- Confirm the identity of the delivery driver from the wholesaler.
- Check that the paperwork supplied by the wholesaler is correct and is for the item and the quantity that was incorrectly ordered or sent.
- Remove the items from the CD cabinet (or other location); remove from the labelled bag and reconfirm the item and quantity to be returned.
- Complete the paperwork, and sign and print name as appropriate.
- For CDs recorded in the CD register, enter the quantity of CDs returned to the delivery driver—include the reference number on the paperwork for audit purposes.
- Confirm that the balance of the product indicated in the CD register matches the actual balance of stock remaining in the CD cabinet.
- Manually update any stock levels held on the pharmacy automatic ordering system to reflect the correct stock levels, if appropriate.

19.10 Damaged stock that cannot be returned to the wholesaler

- This includes damaged stock of liquid CDs.
- Contact the wholesaler immediately (refer to the Pharmacy Tel. directory) before accepting the stock and confirm what the policy is for damaged stock that cannot be returned.
- If the wholesaler insists that the pharmacy accepts the stock due to the delivery driver not being authorised to return any damaged stock, the product must be treated as pharmacy stock and a claim for credit raised with the wholesaler.
- Stock of Schedule 2 CD liquids that is damaged needs to be disposed of in the presence of an authorised witness as soon as possible.
- The authorised witnesses for this pharmacy can be contacted.
- Refer to the SOP "CD: Disposal of pharmacy stock)" for the disposal (including denaturing) of damaged CD stock that cannot be returned to the wholesaler.

19.11 RP not signed in

The RP will be signed in during core and supplementary hours, but there may be an occasion when a wholesaler attempts delivery outside of these hours when other pharmacy staff are still on the premises carrying out other activities.

- Delivery **cannot** be accepted unless the RP is signed in and in control of the process.
- If there is no written authority and/or the wholesaler will not leave CDs without the presence of a pharmacist, contact the RP to establish the time when they will be in control of the pharmacy.
- Contact the wholesaler to inform them that delivery cannot be accepted at the present time and give an approximate time when the RP will be in control of the pharmacy.
- If there has been an attempted delivery of CDs in the absence of the RP, notify the RP as soon as they are present in the pharmacy that there has been an attempted delivery.

19.12 Storage of CDs

- The Responsible Pharmacist takes **overall** responsibility for the CD key and the RP should have the key on them throughout the working day.
- In this pharmacy, CDs are stored in the CD Cabinet.
- The CD cabinet must be kept locked at all times.
- Prescriptions awaiting collection that contain CDs requiring safe custody must be stored in the CD cabinet until collection by the delivery driver, including medicines dispensed in a compliance aid.
- Out-of-date CD stock and unwanted patient CDs requiring safe custody must be clearly marked and segregated from the regular stock.
- The CD cabinet must not indicate on the outside that CDs are contained within.
- At the end of the working day, the CD key is placed in an envelope, signed by the authorised key holder (RP), dated and sealed and handed to the Pharmacy Manager.
- The key is then stored in the safe.
- At the start of the next working day, the CD key holder (RP) should confirm that the envelope has not been tampered with, before opening.

20. Controlled Drugs: Dispensing

20.1 Objective

This SOP looks at the supply of schedule 2, 3, 4 and 5 CDs against prescriptions. This process is intended to be read alongside the Medicine, Ethics and Practice Guide, which gives an in-depth explanation of the legal requirements around the dispensing of CDs.

20.2 Scope

The SOP looks at the dispensing of schedule 2, 3, 4 and 5 CDs against a NHS prescription, private prescription or a requisition.

20.3 Responsibility

Dispensers, Technicians, Pharmacists and Responsible Pharmacist.

20.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

20.5 Process

20.6 Receipt of Prescription

- Refer to the factsheet in Appendix 7 'Controlled Drugs - legal requirements' for guidance on the legal requirements for CD prescriptions.
- Refer also to the factsheet in Appendix 8 'Controlled Drugs - practical guidance'.
- Refer to the normal dispensing SOPs as they form the basis of the dispensing process.
- Confirm the prescription is legally correct and on the correct type of prescription form.
- If the prescription has any legal requirements missing, is out of date, or is written on the incorrect prescription form then contact the prescriber as per SOP 'Interventions and Problem Solving.
- If the error is a typographical error that can be amended then the pharmacist can proceed as follows:
    - The only changes that pharmacists can make are:
        - minor spelling mistakes;
        - minor typographical mistakes (this may include, for example, a number being substituted for a letter or two letters being inverted but where the prescriber's intention is still clear); and/or
        - Where the total quantity of the CD/number of dosage units is specified in either words or figures but not both, a pharmacist can add either the missing words or figures as required (but not both)
    - In doing this, pharmacist must exercise due diligence and be satisfied that the prescription is genuine and the CD is being supplied in accordance with the intention of the prescriber. The prescription must be amended in ink or otherwise indelibly and the pharmacist must mark the prescription so that the amendment is attributable to

him or her, for example by signing the amendment. If there is more than one amendment on the same prescription, each amendment must be marked.

- Where an amendment is made by one pharmacist and another pharmacist makes the supply, the Home Office has advised that the second pharmacist should also mark the amendment to indicate that he is also satisfied and it is attributable to him as well.

- Check that there is sufficient stock of the CD(s) to fulfil the prescription. Follow guidance from SOP 'Prescription Owings'.
- Ensure that the reverse of the prescription has been completed with payment/exemption details. If incomplete, then from reference to the patient's registration documentation, and sign as the representative, if applicable. If proof of exemption has not been provided contact the patient to obtain a copy of this for the records.
    - The driver is then required to sign in the appropriate blue box on NHS prescriptions on collection of Schedule 2 and 3 CDs for delivery.

20.7 Summary Care Record Access

If appropriate, access the patient's Summary Care Record to evaluate the prescription received against the information contained within the record.

20.8 Legal and clinical check of the prescription

- If the prescriber is unknown, contact the prescriber to confirm the validity of the prescription.
- Do not use the telephone number on the prescription — use an alternative source to independently verify the telephone number.
- This pharmacy uses:
    - Directory enquiries: 118 118.
    - NHS Choices website to verify prescriber details.
- If there is any doubt over the authenticity of the prescription, always contact the prescriber in the first instance for advice.
- Minor typographical amendments can be amended by the pharmacist only.
    - See above "Receipt of prescription"
- Prescriptions requiring amendment by the prescriber must be returned to the prescriber for amendment, or a replacement prescription requested.
    - If a replacement prescription has been provided, the incorrect prescription should be destroyed and placed with confidential waste unless it is to be returned to the prescriber.
- If the prescription for a Schedule 2 or 3 CD requests more than thirty days supply, assess the need to verify with the prescriber that there is a genuine clinical need and contact the prescriber if necessary.
    - Update the patient's medication record and make an additional record in the pharmacy intervention book.
    - Include the reasons why more than thirty days supply is considered appropriate.
    - Include details of any conversation with the prescriber, if appropriate.
- If the prescription is presented for dispensing more than two to three weeks after the appropriate date, confirm with the prescriber that there is still a clinical need for the item(s).
- Complete a clinical check of the prescription.

20.9 Labelling and dispensing

- Label and dispense the medicine as per SOP 'Selection, Labelling & Assembly'
  - Break the tamper-evident seal to confirm that the contents of the package are as described if a whole pack is to be supplied.
- Clearly mark any packs that have been split as part of the dispensing process.
- Accuracy check (as per SOP 'Accuracy Check') the prescription and then place in a clear transparent labelled bag, marked with a CD alert sticker.
- Items awaiting collection by the delivery driver/courier that are subject to safe custody requirements must be stored in the CD cabinet until collection.
  - Place a CD alert sticker on the prescription form and store this with other prescription forms awaiting collection.
  - Store any Monitored Dosage Systems containing CD items subject to Safe Custody Regulations in the CD cabinet until delivery is due.
  - Complete the relevant CD delivery manifest paper work (Appendix 5) as per SOP 'Order Delivery'.

20.10 Record-keeping (for Schedule 2 CDs)

- Make an entry in the CD register as soon as possible when issuing to a delivery driver (ensuring that all entries in the CD register are in chronological order).
- Refer to SOP 'Controlled Drugs Record Keeping' for further guidance.
  In this pharmacy, a record of Schedule 2 CDs supplied on a private prescription is recorded in both the CD register (required) AND additionally in the prescription-only register (good practice).

20.11 Delivery to patients

Refer to SOP 'Controlled Drugs Delivery' for further guidance.

21. Controlled Drugs: Delivery

21.1 Objective

To ensure the safe and secure delivery of Controlled Drugs to patients.

21.2 Scope

The delivery of CDs via our company staff and passing of parcels to authorised couriers for delivery.

21.3 Responsibility

Delivery Drivers, Dispensers, Technicians, Pharmacists and Responsible Pharmacist.

21.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

21.5 Delivery of Schedule 2 & 3 CDs

A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

- CDs should be in a separate bag to any other medication being delivered and the bags should be attached together.
- CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.
- The delivery van must be kept locked at all times when the driver is not in the vehicle.
- The delivery driver/courier should sign the back of the prescription as the representative when accepting the CD for delivery.
- The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.
- Any falsified medicines rules introduced by the UK must be followed
- All entries in the CD register should be made when the medication leaves the pharmacy premises. The delivery driver/courier should be entered as the 'person collecting'.
- The prescription should be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier.

21.6 Successful Schedule 2 & 3 Delivery

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure.

21.7 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate.

21.8 Unsuccessful Schedule 2 & 3 Delivery via courier

Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy.

21.9 Note re Use of Couriers for Controlled Drugs Deliveries

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores.

22. Controlled Drugs: Collection and Disposal of Patient Returns

22.1 Objective

To ensure the legal requirement around the correct records keeping, storage and method of destruction are complied with for patient returned CDs.

22.2 Scope

The collection and disposal of patient returned CDs including schedule 2, 3, 4 and 5 drugs.

22.3 Responsibility

Delivery Driver, Dispensers, Technicians, Pharmacists and Responsible Pharmacist.

22.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

22.5 Patient Returned Medication

- This service is available to all patients living in England.
- Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.
- Patients should be referred to the 'Returning unwanted medication' page on the website for information.
- To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this should always be the pharmacist on duty.
- The process for returning medication should be explained to the patient.
- Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician.
- Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them.
- Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to pharmacy.
- Patients should be advised to mark the package of unwanted medication "Z Returns" to allow them to be easily identified. The packaging should not identify the contents as being controlled drugs (or any other drugs).
- Appropriate packaging should be sent to patients to return hazardous medicines as return of such medicines in inadequate packaging may be unsafe.
- Advise patient of their other options to dispose of unwanted or expired medication if they cannot arrange a suitable time for collection. Patients are permitted to return medication to their local pharmacy if required.

22.6 Process

22.7 Return by Royal Mail

The pharmacist must

- Speak to the patient about the return and clarify the items being returned.
- Assess the items for suitability for return by Royal Mail
- If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)
- If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.
- Send the packaging to the patient along with the instructions for appropriate packing of the goods
- Contact the patient to ensure that the packaging has been received
- Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally.

22.8 Handling Patient-Returned CDs from Delivery Driver

Drivers need to:

- Be aware that they cannot accept patient returns from patients without prior arrangement. The driver should notify the patient to follow the "returning unwanted medication" process as set out on the website.
- Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.

Pharmacy staff need to:

- If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.
- As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date.

22.9 Sorting patient-returned Schedule 2 and 3 CDs

- Unwanted patient-returned medicines that include CDs must be handled in the pharmacy by the Dispenser, Technician, Pharmacist or the Responsible Pharmacist only.
- The designated returns area must be used to process all returns.
- Always use the correct Personal Protective Equipment (gloves, apron and mask)
- Empty the bag or container out onto a clear, enclosed surface — never remove medicines by putting a hand directly into the bag (in case sharps are present).
    - If sharps are present contact the local Environment Agency Officer.
- Immediately prior to destruction, identify any Schedule 2 CDs because records will need to be made in the register "Controlled Drugs — record of destruction of returned medicines", or equivalent (but NOT the main CD register).

22.10 Record keeping for patient-returned Schedule 2 CDs

- Enter details of the name, form, strength and quantity of the Schedule 2 CD in the CD returns register together with the date the drugs were returned, and where available, the name and address of the patient and the role of the person returning the drugs (if not the patient).

- State the details of the destruction — the name and position of the person carrying out the destruction together with the name and position of the witness. Both need to sign and date the register to verify the destruction.
    - Retain the records for the minimum number of years as specified by the local AO.
- Destroy all patient identifiable information (for example, the patient's name and address) by disposing of confidentially, for example, shredding in a suitable shredder, incinerating or by obliterating the information with an indelible pen or stamp.
    - This includes information on dispensing labels, monitored dosage system or compliance devices, and so on.

22.11 Denaturing and disposal of patient-returned Schedule 2, 3 and 4 CDs

- The denaturing procedure should be carried out by one person and witnessed by another; the destruction of Schedule 2 patient-returned CDs must be recorded.
- Put on appropriate protective clothing (gloves, apron and mask, for example)
- Remove any patient-returned CDs awaiting destruction from the CD cabinet.
- Denature CDs using an approved CD denaturing kit.
- Follow the instructions on the denaturing kit.
- Return the denaturing kit containing the CDs to the CD cabinet until denaturing is complete (guidance on this should be in the denaturing kit's instructions).
- The CD denaturing kit (or denatured drug) should be placed in the DOOP Storage area (quarantined from normal stock marked with red tape).
- Dispose of gloves, apron and other disposable protective clothing with the pharmacy's clinical waste.
- Wash hands thoroughly.
- Re-order additional denaturing kits if required.
- In the event of untoward events such as spillage or a needle stick injury, refer to the section "Needle stick injury and emergencies" in the SOP 'The safe and effective disposal of medicines'.

22.12 Patient-returned CDs that form part of a dispensing incident

- Patient-returned CDs that form part of a dispensing incident will need to be retained in the pharmacy for the duration of time specified by the local AO.
    - Refer to SOP "Dealing with incidents".
    - Retain the medicine involved according to the SOP 'Controlled Drugs: Record keeping' for CDs but do NOT destroy.

23. The Safe and Effective Receipt and Disposal of Medicines

23.1 Explanatory Note (see PSNC website)

The Pharmacy will comply with all relevant waste management legislation, including:

- **Registration of their conditional exemption to store waste pharmaceuticals returned from households and by individuals, with the local office of the Environment Agency (in line with the requirements of paragraph 39 (1) of the Waste Management Licensing Regulations 1994 (as amended). Registration of the conditional exemptions does not currently incur a charge.**
- **Securely storing waste medicines (including those which are special waste) which have been returned to the pharmacy from households or by individuals for no longer than six months and not exceeding 5 cubic metres in volume at any time.**
- **Retaining Special Waste consignment notes (and any associated lists or schedule) on a register for a period of not less than three years.**
- **Retaining descriptions and transfer notes for at least two years.**
- **Registration of the pharmacy/company as a waste carrier with the local Environment Agency office if the pharmacy/company carries waste medicines from peoples' homes/residential homes back to the pharmacy.**

Staff must be made aware of the risk associated with the handling of waste medicines and the correct procedures used to minimise those risks

Appropriate protective equipment, including gloves, overalls and materials to deal with spillage, should be readily available close to the storage site.

23.2 Purpose

This SOP has been designed to ensure the safe and effective receipt and disposal of returned medication with the aim to minimise any harm to staff involved in the process.

As the pharmacy will collect unwanted medicines it will have the necessary regulatory approvals for carrying waste in place prior to the commencement of services.

This SOP does **not** cover the topic of dealing with waste controlled drugs – these are dealt with in two separate SOPs.

'Controlled Drugs: Disposing of Patient Returns'.
'Controlled Drugs: Disposal of Pharmacy Stock'.

23.3 Scope

This procedure deals with the disposal of medicines, except Schedule 2, 3, 4 and 5 CDs.

23.4 Responsibility

Delivery Drivers, Dispensers, Technicians, Pharmacists and Responsible Pharmacist.

23.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

23.6 Process for Patients to Return Medication

- **Patient Returned Medication**
  - Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.
  - This service is available to all patients living in England.
  - Patients can be referred to the 'Returning unwanted medication' page on the website for information.
  - To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

- **Patients may**
  - Arrange collection by the Pharmacy driver at an appointed time, or
  - Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,
  - The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.
  - Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).

- **Explaining the Process to Patients**

- Check which patient or patients the medication belonged to.
- Check the relevant PMR to identify any hazardous / dangers drugs or items that have been dispensed and could potentially form part of the return.
- Ask the patient to identify the type of medication being returned.
- If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.
- Go through the "unwanted medicines card" (available from the PSNC website) over the phone with the patient

Returning your unwanted medicines to this pharmacy	
TEXT TO SAY TO PATIENT "In order to protect the safety of our staff, customers and the environment, when returning your unwanted medicines to this pharmacy, please take a moment to answer these quick questions. You must be able to answer all the questions with a "**Yes**" in order for our staff to accept your unwanted medicines. Please tell our pharmacy staff if there are any questions to which you've answered "**No**"."	
Are you returning **only** medicines?	Yes☑ No☑
Are you sure there are **no** needles or other sharps in the bag/container?	Yes☑ No☑
Are you sure there is nothing else that may affect the health and safety of our staff?	Yes☑ No ☑

Staff should go through the following list with patients:

✓	**Yes we can accept**	×	**No sorry we can't accept**
✓	Any unwanted medicines including:	×	Needles or other sharps
✓	Tablets	×	Chemicals
✓	Creams	×	Veterinary products
✓	Liquid medicines	×	Dialysis kits
✓	Powders	×	Paints
✓	Inhalers	×	Solvents
✓	Ampoules	×	Oil
✓	Ointments	×	Batteries
✓	Capsules	×	Pesticides or other garden chemicals
		×	Anything else which is not a medicine

Patients should be advised to contact their local council for advice on the safe disposal of products that the Pharmacy cannot accept.

- Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them.
- Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs (see separate SOP), must be separated if possible before the unwanted medication is collected.
- Arrange for suitable packaging to be sent to the patient to place returned medication in to.
- Patients should be advised to mark the package of unwanted medication to "Z Returns" to allow them to be easily identified.

23.7 Process for accepting patient returns by the Driver

- Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.
- Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags
- Wear appropriate protective clothing where there is a requirement to handle any returned waste.
- Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.
- Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.
- Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).
- Identify any flammable waste and store separately until this can be removed by the waste contractor.
- Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.
- Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.
- Store returned medicines in the quarantine area of the van for transport.
- The returnable items can be taken back to the pharmacy for destruction.
- Ensure medicines are not visible in the vehicle at all times

23.8 Patient Returned Medication

- This service is available to all patients living in England.
- Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.
- Patients should be referred to the 'Returning unwanted medication' page on the website for information.
- To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this should always be the pharmacist on duty.
- The process for returning medication should be explained to the patient.
- Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician.

- Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them.
- Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to pharmacy.
- Patients should be advised to mark the package of unwanted medication "Z Returns" to allow them to be easily identified. The packaging should not identify the contents as being controlled drugs (or any other drugs).
- Appropriate packaging should be sent to patients to return hazardous medicines as return of such medicines in inadequate packaging may be unsafe.
- Advise patient of their other options to dispose of unwanted or expired medication if they cannot arrange a suitable time for collection. Patients are permitted to return medication to their local pharmacy if required.

23.9 Return by Royal Mail

The pharmacist must

- Speak to the patient about the return and clarify the items being returned.
- Assess the items for suitability for return by Royal Mail
- If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)
- If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.
- Send the packaging to the patient along with the instructions for appropriate packing of the goods
- Contact the patient to ensure that the packaging has been received
- Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally.

23.10 Disposal of returned medicines

- Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.
- Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect.

23.11 Hazardous medicines

A list of medicines classed as hazardous that need to be handled with care and separated for disposal can be found at:

- http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf

23.12 Controlled drugs

Refer to SOP Controlled Drugs: Disposal of Patient Returns).

23.13 Expired pharmacy waste

- Ensure date expired stock is clearly marked and stored separately from other pharmacy stock.
- Sort pharmacy waste according to the process outlined below.
- Dispose of pharmacy waste according to the process outlined below.

23.14 Disposal of unwanted medicines – Process for Pharmacy Staff

- If you have not already done so, wear appropriate protective clothing – gloves, apron and masks.
- For patient returned CDs see SOP 'Controlled Drugs: Disposal of Patient Returns'.
- For pharmacy expired CDs see SOP 'Controlled Drugs: Disposal of Pharmacy Stock'.
- Destroy all patient identifiable information either by shredding or by obliterating patient identifiable information. The use of marker pens is not permitted as this is not always reliable.
- For sharps received unintentionally:
    - Do NOT remove needles from syringes – place the whole syringe into the sharps container.
    - Dispose of sharps in an appropriate sharps container – where possible it is good practice to use:
    - Purple lid sharps container for sharps contaminated with cytotoxic or cytostatic hazardous medicines.
    - Yellow lid sharps container for sharps contaminated with non-hazardous medicines
    - Orange lid for sharps which are not contaminated with medicines.

- **For liquid medicines:**
    - Do not decant liquids from bottles into the waste container as the mixing of incompatible liquids into a single container could result in fire, release of fumes or explosion and harm to your staff or even prosecution could result.
    - Empty bottles that have contained liquids should also be placed into the waste medicine container as they will contain a residue of medicine.

- **For solid dosage forms:**
    - Do not 'deblister' i.e. remove individual tablets or capsules from blister packaging before placing the waste medicines into the waste disposal container. (This could be regarded as 'waste treatment' which could require a licence).
    - For tablets or capsules contained within bottles – place the whole bottle into the waste container.
    - Where applicable remove the blister strips from the outer cardboard carton and place the intact blister strips into the waste container.
    - Disposable MDS strips should be placed intact into the waste container.
- Separate any hazardous medicines or chemicals and dispose of in accordance with guidance from your waste contractor.
- Dispose of gloves and apron if applicable.
- Thoroughly wash hands.

23.15 Dealing with full containers

- When full, seal the disposal container and store in a safe place, away from empty containers, ready for collection. Full disposal containers awaiting collection are located in the quarantined storage area.
- If the waste containers are full and the collection date is not in the near future, contact waste collector's co-ordinator to arrange a collection (check with RP for waste management company contact details).
- Make a record of the waste consignment on the appropriate form. This is kept in the filling cabinet.
- Complete the required information on the consignment note for hazardous waste. You can either list each item of hazardous waste individually or use a standard continuation sheet.

- Complete the waste transfer sheet (for non-hazardous waste).
- Check that the number of containers has been correctly completed.
- Copies of all documentation supplied or completed by the pharmacy or approved waste collector, including the consignment note (for hazardous waste) and the waste transfer note (for non-hazardous waste) must be kept for three years.

Disposal of controlled drugs

This SOP does not cover the disposal of controlled drugs – see separate SOP.

23.16 Needle stick injury and emergencies

- Wear gloves when assisting an injured person.
- Encourage the wound to bleed and wash it under running water.
- Keep the offending sharp for analysis.
  The injured person should attend the nearest accident and emergency department immediately.
  Record the accident in the pharmacy's accident book which is located in the filling cabinet.
- Make an initial report to the insurance company if appropriate. Contact details for the insurance company are in the filling cabinet.

24. Support for Self-Care, Signposting and Health Promotion

24.1 Scope

The scope of this SOP will include guidance for the provision of self-care to patients and their families, including signposting to appropriate supporting organisations and promotion of a healthy lifestyle including health campaigns.

24.2 Objective

Implementing this SOP will ensure:

- Ensure Services are provided without face to face contact between pharmacy staff and the patient or their representative.
- Enhanced access and choice for patients who want to care for themselves and their families.
- Provision of appropriate advice to people including carers to help them to self-manage a self-limiting or long term condition.
- Provision of information and advice to people who require assistance of appropriate health and social care providers or support organisations.
- Increased patient and public knowledge and understanding of key healthy lifestyle and public health messages.
- Opportunistic provision of health promotion advice to encourage patients to take action to improve their health.
- Patients manage their condition by being more knowledgeable about treatment options
- Patients contact and access further care and support.
- Reduction in inappropriate use of health and social care services.
- To ensure compliance with the Pharmaceutical Services Regulations.

24.3 Applicable to:

Dispensing Assistants, Dispensing Technicians, Accuracy Checking Technicians, Pharmacists.

24.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

24.5 Support for Self Care

24.6 Service Description

The provision of advice and support by pharmacy staff to enable people to derive maximum benefit from caring for themselves or their families.

24.7 Aims and intended service outcomes

- To enhance access and choice for people who wish to care for themselves or their families.

- People, including carers, should be provided with appropriate advice to help them self-manage a self-limiting or long-term condition, including advice on the selection and use of any appropriate medicines.
- People, including carers, are opportunistically provided with health promotion advice when appropriate, in line with the advice provided in "Promotion of healthy lifestyles" service.
- People, including carers, are better able to care for themselves or manage a condition both immediately and in the future, by being more knowledgeable about the treatment options they have, including non-pharmacological ones.
- To minimise inappropriate use of health and social care services.

24.8 Patient Identification

- Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.
- **Active patients** will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.
- **Passive patients** are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.
- **As part of repeat dispensing process / medicine sale or during any other interaction with a patient** staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:
  - treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and
  - on changes to the patient's lifestyle.

24.9 Service outline

- Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.
- If appropriate, access the patient's Summary Care Record to see if it assists in delivery of the service.
- Advice should be backed up, as appropriate, by the provision of written material such as leaflets.
- When such a request is received, the pharmacist should be informed and a record kept of the request.
- Advice (and requests for advice) must operate without face-to face interaction (eg telephone, Live video, via the website).
- The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions.
- Remember that when giving this advice you should also consider healthy lifestyle interventions opportunistically when appropriate, in a similar manner to that provided in "Promotion of healthy lifestyle" service.

- Where appropriate the pharmacist should signpost patients to other health and social care providers, when appropriate (in line with the service provided in "Signposting").
- Records of advice given, products purchased or referrals made will be made on a patient's pharmacy record when the pharmacist deems it to be of clinical significance. However, it is good practice to record details of these interactions even where the interaction does not appear to be of clinical significance.

24.10 Other Provider Organisations and Support Details

Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email.

24.11 Health promotion zone on our website

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients.

24.12 Signposting

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral.

Aims and intended service outcomes

- To inform or advise people who require assistance, which cannot be provided by the pharmacy, of other appropriate health and social care providers or support organisations.
- To enable people to contact and/or access further care and support appropriate to their needs.
- To minimise inappropriate use of health and social care services and support services

24.13 Patient Identification

- Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

- Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:
  - requires advice, treatment or support that we cannot provide; but

- we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible.

24.14 Items Requiring Measuring and Fitting

Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)

24.15 Referral Notes

Where appropriate, a referral may be made by means of a written referral note. The RP will consider each case and decide whether this is appropriate or not and what form any referral note should take.

24.16 Records

Staff should create and keep a record of any information given or referral made and mark an appropriate follow-up date on the PMR system (to be confirmed in each case by the RP).

25. Promotion of Healthy Living, Lifestyle & Health Campaigns

- If it is appropriate to provide healthy living and lifestyle advice, the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on an Intervention & Referral form as part of the PMR. Where this advice includes information in a NHS England campaign this should be recorded.

- If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation. Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

- This is known as a "prescription linked intervention".

25.1 Service Description

The provision of opportunistic healthy lifestyle advice and health advice to patients receiving prescriptions who appear to:

- have diabetes; or
- be at risk of coronary heart disease, especially those with high blood pressure; or
- who smoke; or
- are overweight, and
- pro-active participation in national/local campaigns, to promote public health messages to pharmacy users during specific targeted campaign periods.

25.2 Aims and intended service outcomes

To increase patient and public knowledge and understanding of key healthy lifestyle and public health messages so they are empowered to take actions which will improve their health.

To target the 'hard to reach' sectors of the population who are not frequently exposed to health promotion activities in other parts of the health or social care sector.

25.3 Identification of patients for promotion of Healthy Lifestyles

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone.

Summary Care Record Access - If appropriate, access the patient's Summary Care Record to see if it assists in identifying what areas to provide advice on.

25.4 Health Campaigns & Community Engagement Exercise

Terms of Service require participation in up to 6 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England.

Pharmacy Staff Should

- When a campaign is started:
  - Identify relevant patients that may benefit from additional information during the campaign or the specified clinical audit by cross referencing with the PMR system and advertising the campaign on the website at the "Public health Campaigns" page.
  - Arrange for relevant leaflets to be included with deliveries to relevant patients.
  - Mark each relevant patient's PMR with the marker that shows that they are receiving

information as part of the campaign.
- Ensure that the website has the relevant links updated as each new campaign starts

- A record of the advice given must be recorded onto the PMR system and patients will be reviewed on their conditions at regular intervals throughout the year.
- Recording of advice given should be done in a format similar to that of the MUR form (Intervention and Referral), and the consultation will be carried out over the phone or via video call.
- Record numbers of patients who have taken part in the campaign
- Record keeping ensures the safe and effective continuity of care for patients without the need for face to face contact.
- Provide feedback on the clinical audit in the manner specified in the program guidelines, including anonymised information which is reasonably requested by the NHS

25.5 Process

- Remember it is important to maintain patient confidentiality at all times. Where sensitive or confidential information needs to be discussed with the patient, any member of staff making the call should use a private area to prevent other members of staff overhearing.
- All support for self -care, signposting and health promotion should be carried out by either telephone or email and attempt to assist the patient using the following SOP or refer them to the 'Health Info' section of the website if the appropriate information is posted.
- Answers to questions posed during all interactions must be recorded on the PMR system
- Leaflets regarding current campaigns should be sent (as appropriate) with prescription or P Med deliveries
- Email messages should promote the targeted campaigns that the Pharmacy is involved in and encourage the patient to complete the Lifestyle Questionnaire on the website.
- All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

25.6 Minor Ailments

- Follow WWHAM questions to ensure all necessary information is acquired.
- **Consult with the pharmacist if necessary** – refer to the Medicines Sales SOP for information on when this may be appropriate.
- Give any appropriate advice that you are trained competent to give as well as suggesting appropriate products. If you are unsure about anything always consult the pharmacist.
- Record any appropriate consultations in the Interventions and Referrals book.
- Complete manual order with all relevant fields.

25.7 Long Term Conditions

- **If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency.** Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.
- If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be

provided it should be recorded on an Intervention & Referral form along with the referral organisation.

- For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets.

25.8 Identification of patients for Support with Long Term Conditions

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles.

Summary Care Record Access - If appropriate, access the patient's Summary Care Record to see if it assists in identifying what areas to provide advice on.

26. Discharge Medicines Service ("DMS")

PREPARED WITH REFERENCE TO NHS ENGLAND GUIDANCE DOCUMENT and PSNC GUIDANCE

26.1 Service Description

When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.

Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient

(a) recently discharged from hospital who is referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or

(b) who is otherwise referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.

The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.

The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.

If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or re-admission to hospital).

26.2 Aims and intended service outcomes

- optimise the use of medicines, while facilitating shared decision-making
- reduce harm from medicines at transfers of care
- improve patients' understanding of their medicines and how to take them following discharge from hospital
- reduce hospital readmissions

26.3 Process

Every day the RP must check the pharmacy's NHS mail system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen".

26.4 Consent

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP.

26.5 DMS Stages

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process.

26.6 DMS Stage 1

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral.

26.7 Considering the appropriateness of any medication changes prior to discharge

- DMS requests will not necessarily all be in the same form.
- Summary Care Record Access - If appropriate, access the patient's Summary Care Record to see if it assists in providing the service
- The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.
- For actions that are considered appropriate the pharmacist must;
    - Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.
    - Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.
    - Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—
      (i) the staff of the hospital or other provider of NHS services that made the referral, and
      (ii) any provider of primary medical services on whose patient list the patient is; and
    - keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHSE GUIDANCE

26.8 DMS Stage 2

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy as received a request for Stage 2 of the DMS service either from Stage 1 or

- Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 that this is the

first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

- The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

- Review / perform a further review of any prescription
- Summary Care Record Access - If appropriate, access the patient's Summary Care Record to see if it assists in providing the service.
- Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.
- Where you see areas of concern, raise those issues as appropriate with the patient's GP
- Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service).

26.9 DMS Stage 3

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines.

26.10 Additional advice, assistance and support

When the pharmacy either receives a prescription (in whatever form) or has been made aware via a referral to the DMS that a prescription is the first prescription for a medicine that has been made following the patient's discharge from hospital, or where the patient's care has been transferred from another NHS service provider, the following steps must be followed:

- Summary Care Record Access - If appropriate, access the patient's Summary Care Record to see if it assists in providing the service
- Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to;
    - Assess the patient / carer understanding of the medicines that the patient should be taking
    - The patient should have received a copy of the prescribed medication from the hospital which lists the medication you are taking. This must match the discharge prescription when written.
    - If changes have been made to the patient's medication regimen, clearly explain the changes.
    - Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall.

- Think about high risk medicines or those where the treatment is more complex and where extra advice and support should be provided – e.g. anticoagulants
- Discuss common or expected side effects
- Discuss the use of medication apps which can be downloaded and may help the patient stick to their treatment plan.
- If injectables have been prescribed and the patient is considered to be able to self-administer these, then have they received appropriate training from their GP practice nurse or hospital?
- Inform the patient / carer about
  - The disposal service offered in respect of unwanted drugs (see separate SOP). This is particularly relevant to medicines which may still be in the patient's home but may no longer be prescribed.
  - Any other pharmaceutical services that the patient or their carer may benefit from following their stay in hospital and / or the transfer of care from another NHS pharmacy

- Follow up
  - Where you identify any areas of concern then to the extent it is appropriate to do so in your clinical judgement, contact the patient's GP to discuss the concerns and consider any appropriate action plan to deal with the concerns.
- In every case it is important to keep and maintain records of the above discussions, concerns and actions taken as part of providing this service and these will also assist in service evaluation processes.

26.11 Things to Consider Across the Stages

This is not intended to be an exhaustive list, but the pharmacist should consider;

- Appropriateness of the medication prescribed. Whilst bearing in mind that changes are likely to have been consultant led and seen by the patient's GP, the pharmacy can offer valuable insights and consider areas that the hospital or GP may not have considered such as stock availability.
- Blister Packs – Are blister packs appropriate for the patient?
- Compliance Aids - Ensure that the patient is able to use devices before supplying them:
- Certain devices may have been used by the patient whilst on the ward (e.g. for self-administration), the patient may be given the device to take home with them to use at home.

26.12 Risks

- Changes in treatment not properly identified.
- Poor understanding of medicines prescribed
- Risk of patient harm from lack of understanding
- Availability of high quality live video link at the patient's home
- Poor communication of medication changes between NHS care providers

26.13 Responsibility

Pharmacists and Pharmacy Superintendent.

26.14 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

26.15 Typical process (subject to patient / medication requirements)

Whilst NHSE guidance suggests that many areas of the process below are suitable for "pharmacy technicians" to carry out, the overlapping nature of the requirements means that the pharmacist should take responsibility for all stages of the process.

STAGE 1 – BEFORE PRESCRIPTION RECEIVED
Check each day for any new referrals
If appropriate check the patient's SCR
Check for clinical information and actions contained in the referral which need to be undertaken. Details of what to look for are outlined in the toolkit which accompanies this service guidance.
Check any previously ordered prescriptions for the patient in the dispensing process or awaiting collection to see if they are still appropriate. Particular attention should be paid to electronic repeatable prescriptions as these could be pulled down from the system sometime after the patient has been discharged from hospital.
Check the referral to compare medicines prescribed before discharge with those prescribed post discharge. Specifically consider any ■ High risk medicines. ■ Newly started respiratory medication, including inhalers. ■ Medication requiring follow-up, eg blood monitoring, dose titration. ■ Patients prescribed medicines that have potential to cause dependence (eg opioids). ■ Those for which doses vary/change, either increasing or decreasing over time.
Consider if the patient is "high risk" eg ■ People taking more than five medications, where the risk of harmful effects and drug interactions is increased. ■ Those who have had new medicines prescribed while in hospital. ■ Those who have had medication change(s) while in hospital. ■ Those who have experienced myocardial infarction or a stroke due to likelihood of new medicines being prescribed. ■ Those who appear confused about their medicines on admission/when getting ready for discharge, and have already needed additional support from a healthcare professional. ■ Those who have help at home to take their medications. ■ Those patients who have a learning disability.

CHECK FOR ■ changes to quantity ■ changes to dosage ■ changes in formulations ■ changes to the frequency at which the medicine should be administered ■ changes to the frequency at which the medicine will be prescribed ■ interactions and contraindications relating to the changed medications ■ appropriateness.
CHECK FOR ■ newly prescribed medication, including considering whether medicines are intended to given long-term or have been initiated for short-term use ■ discontinued medication (including removing medicines no longer needed) ■ planned changes to medicine (eg antibiotics stopped after course is completed) ■ changes to medicine administration route ■ concerns highlighted by the NHS trust, eg intentional non-adherence ■ bloods or other tests needed to ensure safety or check for efficacy.
Identify any issues or concerns and discuss with other healthcare providers at the hospital or patient's GP surgery
Make a record of all actions
STAGE 2 – UPON RECEIPT OF FIRST PRESCRIPTION
If appropriate check the patient's SCR
Check the referral to compare medicines prescribed before discharge with those presented on the prescription
Review the recommended action from Stage 1 of the referral
Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of care from NHS service provider.
Consider if it is appropriate to make an appointment to provide the Stage 3 service to the patient or their carer. If a telephone or video call appointment is arranged ask the patient/carer to have all their medicine(s) with them at the time of that appointment
Make a record of all actions
STAGE 3 – PATIENT / CARER INVOLVEMENT
Each day check the pharmacy diary for any appointments due and appointment reminders to make.
In advance of the intervention: • Review the patient's medication and actions from Stage 1 and 2 as appropriate • If appropriate check the patient's SCR • Send a reminder to the patient / carer
The service should preferably take place via a live video link, but can also be provided by phone if a video link is not available if that is still appropriate. All discussion must take place in a private area where they cannot be overheard by other staff members.

Welcome the patient/carer onto the service and make them feel at ease.
Confirm identity of the patient by using questions such as date of birth and postcode (see separate SOP on confirming identity)
Confirm the patient consents to their information being shared and that they understand the nature of the service.
Explain that this is not a test of the patient / carer's knowledge and that it is a service being provided to them to help them with their health care needs
Ask the patient / carer about their understanding of their medicines and how they believe they should be taken and any changes that have been made
LISTEN - do not use phrases like "Do you take one of these at night to help you sleep". Instead ask questions like "when do you take this tablet and what does it do?" Make notes as you go along. When you understand what the patient or carer believe you can use these notes at the next stage.
Compare this list of medicines with those provided or intended at discharge and record any discrepancies.
Go through all medicines and medication charts with the patient (carer or relative as required), highlighting medicines which have stopped, started or changed. Specifically focus on areas where there appeared to be poor understanding.
Use the information gathered and recorded on each medicine and agree with the patient the appropriate action to resolve any issues: You can **Resolve with the patient** minor issues that were able to be discussed and explained during the service. You can **Contact the GP** where the issue requires an amendment from the GP or intervention of GP practice staff You can **Contact the hospital** where the issue requires hospital intervention Involve the patient /carer in the decision making process and ensure that they agree with the recommended steps to be taken.
If no issues with the patient's medication have been identified dispense required medication in accordance with the relevant SOP for dispensing and counsel as to any changes made by hospital.
Consider and compliance aids required
Consider if it is appropriate to discuss any common or expected side effects from new medication or interactions
Discuss other services available from the pharmacy that the patient and / or their carer might benefit from accessing. Ensure that, where appropriate, the patient understands that these services can be provided to them at no cost.
Consider medicine wastage as patients may have previously received identical medication that may already be in their home:
Explain the Disposal of Unwanted Medicines Service and direct the patient to the relevant page on the website for information.

Ask the patient if they have any further questions or information requirements and confirm the agreed actions and the date and time of the follow-up if required
Consider if a further review is required and if so arrange the appointment and note it in the diary
Ensure any information obtained during the service is recorded accurately on the patient's electronic record.

26.16 Service Examples from NHS Toolkit for Reference

Case study - Providing relevant clinical information

Mrs Ballantyne was admitted to hospital after falling at home. While in hospital, her medicines were discontinued. Prior to discharge, all her usual medicines were restarted except for furosemide (prescribed for heart failure) as her sodium levels were still low. She was referred to the NHS Discharge Medicines Service with a request to restart furosemide when her blood tests were normal. The community pharmacy contacted Mrs Ballantyne and she agreed to get a blood test the following week at her surgery. The blood test results were normal. The pharmacist already had a prescription for furosemide and this was then dispensed.

26.17 Examples of the NHS Discharge Medicines Service process

Example 1

Mrs Patel was referred to her community pharmacy on discharge. The community pharmacist reconciled the medicines with the pharmacy patient medication record and noted that Adcal D3 and GTN spray were missing. The community pharmacist then contacted Mrs Patel and discovered that she had forgotten to take these items into hospital and therefore was not given these medicines. The community pharmacist checked that these medicines were still indicated and did not interact with the new medicines prescribed, and then advised Mrs Patel to continue with the Adcal D3 and to use her GTN spray as needed.

Example 2

Mr Barrett, 90 years old, lives alone has also been referred to the community pharmacy on discharge. On reconciling his medication, the community pharmacist noticed that metformin was missing from his discharge information. The community pharmacist contacted the NHS trust and discovered that it had been withheld due to acute kidney disease. However, recent blood results were normal and therefore Mr Barrett should restart the medicine. The community pharmacist worked with the PCN clinical pharmacist to arrange a new prescription. Mr Barrett was contacted and the community pharmacist arranged a discussion with Mr Barrett to coincide with the collection of his dispensed medicines and ensure he understood his medicines regimen.

Example 3

Mr Fisher was referred following a long stay in hospital. He had several changes to his medicines which were clearly documented on the discharge information. The community pharmacy technician updated Mr Fisher's patient medication record. They noted that there was a prescription for Mr Fisher on the NHS Spine which accurately reflected his post-discharge medicines regimen. This was dispensed and delivered to the patient. A telephone discussion was also arranged by the community pharmacy technician to check Mr Fisher's understanding of his changed medication and for any adverse events.

26.18 Examples where normal flow of patients through the service may not be appropriate

1. A referral is received for a new patient: Where a referral is received for a patient who is new or unknown to the pharmacy, the pharmacy contractor may then need to contact the NHS trust and/or the

patient for more information; and to check that the patient wishes to continue using this pharmacy for the DMS.

2. Patient uncontactable or withdraws consent following completion of stage 1: Where stage 1 of the service has been delivered but the patient withdraws consent to receive the service, or the first prescription post-discharge is not received by the pharmacy contractor to complete stage 2 of the service and no contact is made by the patient, reasonable attempts must be made by the pharmacy contractor to contact the patient using the contact details set out in the referral. In this scenario, it is possible that the patient has been readmitted to hospital, admitted to a care home or has died. Where the pharmacy contractor is unable to reach the patient (or the patient has been readmitted to hospital or admitted to a care home), the pharmacy contractor should share any findings of concern from stage 1 of the service with the patient's general practice.

3. Patient uncontactable or withdraws consent following completion of stage 1 and stage 2: Where stages 1 and 2 of the service are provided by the pharmacy contractor but the pharmacy contractor is unable to contact the patient to complete stage 3 of the service, reasonable attempts must be made by the pharmacy contractor to contact the patient using the contact details set out in the referral. In this scenario, it is possible that the prescription may have been collected by the patient or a representative and either: the patient was unable to discuss their medicines at the point of collection; or the patient/carer does not attend an agreed consultation; or the patient/carer refuses to take calls from the pharmacy contractor; or that the patient/carer states that they do not wish to engage with a consultation about their medicines. Where the community pharmacy is unable reach the patient or the patient withdraws consent to receive the service at this point, the pharmacy contractor should share any findings of concern from stages 1 and 2 of the service with the patient's general practice.

4. Patient moves community pharmacy after stage 1 of the service has been provided: The situation may occur where stage 1 of the service has been delivered by a pharmacy contractor and that pharmacy contractor subsequently finds out that the patient wishes to use a different pharmacy contractor for the provision of the service. The first pharmacy contractor should contact the second pharmacy contractor and offer to send them, via a secure electronic message (eg to the pharmacy contractor's premises specific NHSmail account) and with the patient's consent, the referral information received from the NHS trust and any relevant information and/or findings identified during stage 1 of the service. The same approach could be taken if another pharmacy contractor contacts the first pharmacy contractor to inform them that the patient has asked them to dispense the first prescription post discharge.

5. Temporary community pharmacy closure means that the complete service cannot be provided: Where a temporary community pharmacy closure of one week or more means that a pharmacy contractor cannot provide the service, reasonable attempts must be made by the pharmacy contractor to contact the patient using the contact details set out in the referral. The pharmacy contractor should inform the patient of the situation and identify another pharmacy contractor to refer the patient for completion of the service. In these circumstances, the pharmacy contractor should contact the identified pharmacy contractor and offer to share, via secure electronic message (eg to the pharmacy contractor's premises specific NHSmail account) and with the patient's consent, the referral information received from the NHS trust and any relevant information and/or findings identified during stages 1 or 2 of the service if already provided.

27. Near Miss

27.1 Objective

To promote good dispensing practice and reduce the risk of customer harm, by preventing dispensing errors. The Near Miss Log should be used as a learning tool to reduce near misses and improve patient safety.

27.2 Scope

To detail the procedure to be followed for all dispensing errors found in the pharmacy before medication is dispatched to the patient.

27.3 Risks

- Near misses not reported resulting in the problem re-occurring.
- Near misses not resolved appropriately and damaging the reputation of the Pharmacy.
- Failing to identify a near miss resulting in patient harm.

27.4 Responsible

Dispensing Assistants, Dispensing Technicians, Accuracy Checking Technicians, Pharmacists and Pharmacy Superintendent.

27.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

27.6 Process

A Near Miss is any error discovered during the dispensing process before the prescription is delivered to the patient.

27.7 Near Miss Identified

- Once identified the Near Miss should be corrected following dispensing SOPs and the checking process restarted to ensure there are no further errors
- ALL Near Misses should be recorded on the Near Miss Log by the person who made the error, reflecting on why the error was made.

27.8 Near Miss Reviewing

- The Near Miss Log should be reviewed weekly to identify any common themes or trends in the near misses that occur and an action plan made to address any issues identified and improve pharmacy practice.
- The Near Miss Logs should be reviewed monthly with the Pharmacy Superintendent to ensure best practice is followed and highlight the need to change any practice within the pharmacy.

28. Customer Complaints

28.1 Objectives

This SOP is designed to help deal with customer complaints in a professional and timely manner to avoid unnecessary escalation.

28.2 Risks

The risks of not dealing with customer complaints appropriately may result in damaging the reputation of the Pharmacy and failings to provide the highest level of customer care.

28.3 Scope

This SOP has been designed to comply with legislation and therefore must be adhered to where complaints arise relating to the provision of NHS services by the pharmacy business.

Legitimate complaints could include issues related to the provision of the NHS services – such as attitude of staff on the phone or drivers or even having to be owed medication.

This SOP may also be used for private complaints – for example a complaint arising from the sale of a herbal supplement or an Online Doctor purchase.

This SOP does NOT apply to:

- A complaint made by an employee about their employment.
- A repeat complaint which has already been previously investigated under these procedures or any previous relevant complaints procedure.
- A complaint which relates to an alleged failure to comply with Freedom of Information Act 2000.
- A complaint made directly by a Responsible Body (local health authority, NHS body, HSC organisation, primary care provider or independent provider).

Where a complaint is related to a dispensing error or incident, refer also to the SOP 'Dealing with an incident'.

28.4 Responsibility

Responsible Pharmacist, Pharmacy Manager and Superintendent Pharmacist.

28.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

28.6 Duty of Candour

Health professionals must be open and honest with patients when things go wrong. This is also known as 'the duty of candour'.

Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.

This means that healthcare professionals must:

- Tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong
- Apologise to the patient (or, where appropriate, the patient's advocate, carer or family);
- Offer an appropriate remedy or support to put matters right (if possible); and
- Explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short and long term effects of what has happened.

Healthcare professionals must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested.

Health and care professionals must also be open and honest with their regulators, raising concerns where appropriate.

They must support and encourage each other to be open and honest and not stop someone from raising concerns.

28.7 Process

- **Handling of customer complaints**
  - Patients or their representatives must not access the pharmacy directly to make any complaints. Any person seeking to do so must be provided with the contact details of the pharmacy and asked to make all communication via non face to face channels.
  - Always ensure that a customer complaint is escalated to a senior member of staff or pharmacist.
  - Complaints about pharmaceutical services should be referred to the Responsible Pharmacist or Pharmacy Superintendent.
  - Every effort should be made to rectify the complaint as soon as possible with the welfare of the customer being the first priority.
  - Always attempt to resolve the complaint on the telephone, rather than by email, to avoid miscommunication. In the event of a serious incident the patient may be visited at their home if they desire.
  - Accurate and contemporaneous records of all communication should be kept for future reference.
  - Advise patients that they can complain directly to NHS England and provide them with contact details to do so.

- **Receiving a complaint**
  - Receive complaints with respect and courtesy.
  - Treat complaints as confidential.
  - Accept complaints made orally or in writing or if made electronically.
  - Establish whether the complainant has grounds for making a complaint.
  - NB – in practice this may be instantly apparent without the need for analysis or further questioning to establish. However if analysis is required then in order to have grounds for a complaint an affected person must have been affected by an action, omission, or decision of the pharmacy OR must have received services (private or NHS/HSC) from the pharmacy.
  - If there are no grounds for complaint and the pharmacy does not need to proceed with the complaint.

  Once grounds for complaint have been established – confirm whether the complaint is being made by the affected person or by a representative.

- Where the complaint is made by a representative, determine if:

- The affected person has died
- The affected person is a child and there are reasonable grounds for the complaint to be made by the representative.
- The affected person lacks mental or physical capacity to complain directly and there are reasonable grounds for the complaint to be made by the representative.
- The affected person has requested that the representative acts on their behalf.
- The complaint has been referred from the CCG, Health Board or another HSC organisation following a complaint which they received directly from the affected person or representative.

Where none of these conditions apply, then the pharmacy does not need to proceed with the complaint, however a written notification must be supplied to the representative stating the reasons for not proceeding.

- Check whether the complaint has been made within the time limit

  In **England** – a complaint is valid for up to 12 months after the event OR up to 12 months after the complainant realised that they had an issue to complain about.

  However (applicable across the UK) - If the pharmacy is satisfied that there are good reasons for not making the complaint within the time limit AND it is still possible to investigate the complaint effectively and fairly then the time limit does NOT apply.

  Where the time limit has lapsed and the exception does not apply then the pharmacy does not need to proceed with the complaint. A written notification should be supplied to the representative stating the reasons for not proceeding.

  Irrespective of time limits, the Pharmacy should always try to investigate any complaint made as it is vital for the public and the profession that patients can trust in the services they receive from the pharmacy and feel confident that any problems they may raise are taken seriously. The pharmacy must not attempt to 'hide behind' time limits when dealing with complaints.

- Where appropriate – relay details of the complaint to the indemnity provider (e.g. NPA Insurance). Keep them informed of developments as they arise.

- The pharmacy should also supply contact details for organisations that can provide independent advice and support with making the complaint.

- **Dispensing errors**
  - Attempt to resolve the complaint by talking to the customer on the telephone. NB the person dealing with the complaint must be aware that no Essential Services may be provided via face to face contact.
  - The customer should be given a chance to voice their concerns with your full attention.
  - Always apologise to the customer if the level of service is not up to their expectations or our high standards.
  - Do no try to transfer the blame or admit Liability.
  - In the event of a dispensing error try to establish the following information:
    - Who is the patient?
    - What is the nature of the error?
    - Who dispensed and checked the incorrect item?
    - Has any of the incorrect medication been taken?
    - If so, how much and has there been any ill effects?
    - Is there likely to be a clinically significant interaction with any of the patients prescribed medication?
  - If any incorrect medication has been taken the pharmacist must contact the prescriber and the Pharmacy Superintendent to agree upon action to be taken.

- Where possible the incorrect medication should be returned to the pharmacy for inspection and the packaging retained for 2 years.
- A new supply can be made using the original prescription where appropriate.
- Advise the customer that all complaints will be reported to the Pharmacy Superintendent and investigated accordingly.
- Establish whether a response from the Pharmacy Superintendent is required.

All customer complaints must be reported to the Responsible Pharmacist and Pharmacy Superintendent.

- It is important to establish if SOPs have been followed in the process leading up to the customer complaint.
- After an audit of the complaint practice should be assessed to prevent the incident from re-occurring.

- **Delivery of Damaged Medication**

  - If a patient contacts The Pharmacy to report that a prescription has been delivered and the medication was damaged in transit the patient should be advised to return the medication to the Pharmacy as it was received. Returns must be made in accordance with the relevant SOP and cannot be made in person, ie no face to face contact may occur between the patient or their representative and the pharmacy.
  - The RP can inspect the medication when it is received and if satisfied they can authorise it to be redispensed and deliver.
  - The patient should be contacted by telephone to advise them of the new delivery date.
  - If the medication is urgent then the RP should contact the prescriber about the possibility of issuing a new prescription to ensure the medication arrives in a timely fashion.
  - A record should be made on the patients PMR of the details of the incident and the resolution. An Intervention sheet should also be filled in.

- **Non-Arrival of Dispatched Medication**

  - If a patient contacts the pharmacy regarding the non-arrival of medication that has been dispatched from the warehouse Royal Mail should be the first point of contact.
  - Using the tracking number specific to that patient Royal Mail should be able to locate the package and advise when it will be delivered, this should be relayed to the patient.
  - If Royal Mail has lost the parcel, the RP should contact the prescriber to explain the situation and arrange a new prescription to allow re-dispensing of the medication.
  - Telephone the patient to apologise and explain the situation to them. Inform them of the new expected delivery date.
  - If the parcel has not been delivered within 15 days of dispatch a claim should be opened with Royal Mail for the value of the parcel.
  - A record should be made on the patients PMR of the details of the incident and the resolution. An Intervention sheet should also be filled in.

Establishing whether the complainant has grounds to make a complaint

- Dealing with an oral complaint over the phone

  - Oral complaints may be received by phone. Where possible try to resolve the complaint by:
  - Listen carefully to the complaint.
  - Respond politely to the complaint.
  - Using appropriate tone to convey understanding and sympathy.
  - Where possible investigate and deal with the complaint immediately i.e. “on the spot” balancing disruption to the pharmacy with delay for the patient.

- Consider whether the pharmacy is at fault or is partially at fault. Where you are satisfied that there is cause for the complaint or a mistake has been made consider a careful apology where appropriate being careful **not** to admit the consequences of the cause for complaint (i.e. that a dispensing error has led to clinical condition x, y and z).
  - I am sorry that you have cause for complaint.
  - We are sorry that we have made a mistake.
- Where it is unclear whether there is cause for a complaint or if a mistake has been made:
  - I'm sorry that you are upset

- Where an oral complaint is received over the phone **and** resolved to the satisfaction of the complainant immediately or within the next working day then no further action is required. NB staff will often find the information they gain from complaints resolved useful in improving service quality.
- If the oral complaint received by phone has **not** been resolved then:
  - A written record of the oral complaint must be made.
  - The complainant must be supplied with a copy of this written record.
  - The remainder of this formal complaints procedure applies.
- Dealing with a written complaint, an electronic complaint or an unresolved oral complaint

  Where a complaint relates to the actions of more than one NHS body; the complaints manager should notify the other bodies involved and co-ordinate and co-operate, sharing information and meeting where required to consider the complaint and to agree on the best approach to investigation and resolution. A lead organisation should be identified and it may be possible to divide aspects of a complaint between organisations. The complainant must be kept informed and provided with advice about how each aspect of their complaint will be dealt with and by whom.
  - Carefully read the details of the complaint.
  - England only - Where the complaint is related to the provision of NHS services then record the date the complaint was received and the subject of the complaint into the NHS Complaints Record: England (NPA product available from NPA Sales - CRB001).

28.8 Acknowledging a complaint

- Acknowledge the complaint in writing within 3 working days (**Wales 2 days)** after the complaint is received. Where appropriate this can be done immediately after the complaint is received.
- The acknowledgement should:
  - Be conciliatory.
  - Confirm the issues raised in the complaint.
  - Offer to discuss issues with a member of the complaints staff or a senior member of staff.
  - Provide information about sources of independent advice and support (see appendix 3)
  - Indicate that a full response will be provided within (**Scotland and Northern Ireland** - 10 working days) (**Wales** – 20 days) (**England** – no statutory period – suggested 20 days).
- **England Only** - At the time of the acknowledgement there must be an offer to discuss the following at an agreed time:
  - How the complaint will be handled.
  - The likely response period for when the completion of the investigation and the final response will be sent to the complainant.

- Where the complaint is related to the provision of NHS services then record the agreed response period into the NHS Complaints Record: England (NPA product available from NPA Sales - CRB001).
- If the complainant unwilling to discuss– then the pharmacy must notify the complainant in writing of those details.

- **Investigation**
  - Take steps to investigate the complaint efficiently and effectively, interviewing colleagues where necessary and establishing a clear factual timeline of events.
  - Inform the complainant about the progress of the investigation where this is reasonably practicable.
  - Where the response period from the date the complaint was received has passed and the pharmacy is not yet in a position to respond to the complaint – then a written notification must be sent to the complainant with an explanation of the reason for the delay.
- **Reporting the outcome to the complainant**
  - Following the completion of the investigation – a report of the outcome must be sent to the complainant in writing as soon as practicably possible.
  - Include within the report:
    - An explanation of how the complaint has been considered.
    - An indication that concerns have been addressed following full and fair investigation.
    - The conclusion of the investigation and any relevant remedial action.
    - Confirmation of whether the pharmacy is satisfied that if any action is required then this has been taken or will be undertaken.
    - An apology where things have gone wrong.
    - Ombudsman where the complaint relates to NHS service provision (HSC services in Northern Ireland).
    - The signature and details of a named senior member of staff. (**In England** the Responsible Person or someone authorised by the Pharmacy Business to perform the functions of the Responsible Person must sign this document).
- **The report must be:**
  - Clear.
  - Accurate.
  - Balanced.
  - Simple and easy to understand.
  - Free from technical terms or if these must be used clearly explained.
- **England only -** Where the complaint is related to the provision of NHS services then record the following into the NHS Complaints Record: England (NPA product available from NPA Sales - CRB001):
  - The outcome of the complaint.
  - The date the report of the outcome was sent to the complainant.
  - Whether or not the outcome was sent to the complainant within the agreed response period.
  - Whether or not the pharmacy consider the complaint well-founded.
- If the complaint is a not related to the provision of NHS services – then depending upon the nature of the complaint referral to an appropriate body should be considered. For example if the complaint relates to a private PGD then the Independent Medical Agency or Care and Quality Commission or if a complaint relates to unsafe packaging then refer to the MHRA or the manufacturer.
- Follow up action

If applicable, consider:

- Review and amendment of SOPs following the procedure outlined in the SOP 'Review and notification of standard operating procedures'.
- Train or brief staff. In some cases you may need to consider using the disciplinary process.

- **Record Keeping**

Retain all the following for 10 years (suggested) from the date of completion of the action.

- Correspondence.
- Copies of response sent to the complainant.
- Evidence.
- Details of complainant consent.

28.9 Reporting (Applicable only to NHS or HSC service related complaints)

England only

- In April of each year prepare an annual report for the last 12 months ending on 31st March.
- The report must contain:
  - Number of complaints received.
  - Number of complaints which the pharmacy decided were well founded.
  - The number of complaints referred to the Parliamentary and Health Service Ombudsman.
  - A summary of
    - The subject matter of the complaints received.
    - Important matters arising from the complaints received.
    - Actions to improve services from complaints received.
- A copy of the annual report must be sent to NHS England as soon as reasonably practicable.
- A copy of the annual report must be made available for any person upon request.

PSNC have a template form which can be used for annual reporting. This is available from the PSNC website at www.psnc.org.uk .

29. Dealing with an Incident

29.1 Objective

The purpose of this SOP is to provide a guide to dealing with incidents when they occur and to look at how the damage can be minimised.

29.2 Scope

An incident that occurs in the Pharmacy or in relation to deliveries that are being made by employed staff members. Where a complaint has been made then the incident is also subject to the procedures detailed in the SOP 'Dealing with complaints'.

29.3 Responsibility

Responsible Pharmacist and Superintendent Pharmacist.

29.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

29.5 Process

29.6 Extremely serious or urgent incidents

- Quickly assess the nature of the incident and decide if the circumstances are serious or urgent enough to merit to immediate cessation of sale or supply of medicinal products or closure of the registered pharmacy. *(e.g. if the responsible pharmacist is suddenly taken ill).*
- Consider if the emergency services need to be contacted and contact them where necessary by dialling 999.

29.7 Investigation and recording of an incident

- The following should be investigated and recorded:
  - Date and time of actual incident.
  - Location of the incident if outside the pharmacy premises.
  - Nature of the incident.
  - Factual account of the incident.
  - Name of the pharmacy staff member making the record.
  - Role/job title of the pharmacy staff member making the record.
  - Nature of any alleged involvement in the incident being recorded.
  - Cause of the incident.
  - Actions which could have prevented the incident from occurring in the first instance.
- Where applicable the following should also be investigated and recorded:
  - Name and address of patient(s) affected.
  - Gender of patient(s) affected.
  - Age of patient(s) affected.

- Name and address of prescriber.
- Nature of harm alleged to have been caused to the patient(s) by the incident.
- Name(s) of any pharmacy staff allegedly involved in the incident.
- Role/job title of any pharmacy staff allegedly involved in the incident.
- Name of the responsible pharmacist on duty at the time of the incident.

29.8 Possible contributing factors

- Details of medicines or devices involved in the incident – where applicable:
  - Name.
  - Strength.
  - Formulation.
  - Dose.
  - Batch number.
  - Expiry.
  - Other relevant information.
- Retain medicines, labels or devices where possible.
- Print off PMR records where possible.

29.9 Reporting an incident

- Where an incident concerns a medication error resulting in potential or actual harm to the patient – ensure that the prescriber is informed if this hasn't already been done and make a record that the prescriber has been informed.
- Depending upon the nature of the incident assess whether details of the incident and investigation should be reported to any of the following for follow up and make a record that this has been reported to:
  - The Superintendent Pharmacist.
  - The Primary Care Organisation or Regional Health and Social Care Board (RHSCB) in NI.
  - The indemnity insurance provider.
  - The National Patient Safety Agency (using the eForm found at www.npsa.nhs.uk/eform) *(As part of clinical governance and the pharmacy contract – community pharmacies in England and Wales are obliged to report patient safety incidents to the NPSA).*
  - All complaints must be reported to the PSO via the Incident Reporting System.
  - Changes to the PSI reporting arrangements in 2014/15.
    - In order to help meet NHS England's objectives to improve patient safety, it has been agreed that:
      - there must be an increase in the number of patient safety incidents reported by community pharmacies to the NRLS; and
      - from the implementation date, reports submitted to the NRLS will have to identify the pharmacy making the report.

    The requirements for patient safety incident reporting by community pharmacy contractors are set out in the Approved Particulars. The existing Approved Particulars will be amended from the implementation date to require the identification of pharmacies making reports to the NRLS.

    The Approved Particulars will also be amended to clarify which patient safety incidents should be reported to the NRLS. At present the Approved Particulars

require that all patient safety incidents must be reported to NRLS. This will be amended to clarify that patient safety incidents that did or could have led to patient harm must be reported. Incidents where there was no implied or actual patient harm, for example picking errors that are identified and corrected during the pharmacy's checking procedures, will not be required to be reported to the NRLS.

The superintendent pharmacist must ensure that the new reporting requirements are met from the date that the Approved particulars are changed and ideally before that date.

See http://psnc.org.uk/contract-it/essential-service-clinical-governance/patient-safety-incident-reporting/

29.10 Learning from an incident

- Identify actions which would prevent this incident occurring in the future and where appropriate review the appropriate Standard Operating Procedure and if necessary implement changes following the steps outlined in SOP 'Review and notification of standard operating procedures' to prevent an occurrence carry out a Root Cause Analysis.
- Assess whether it is necessary to train or retrain staff and if so implement training and record that it has been undertaken.
- Assess whether it is appropriate to formally discipline staff and if so implement disciplinary action after taking appropriate employment advice.

Assess if there is a Health and Safety issue which needs to be resolved.

29.11 Feedback over the phone or in writing

- Where the incident leads to a complaint then refer to SOP 'Customer complaints'.
- Consider the use of a careful apology where appropriate being careful **not** to admit the consequences of an incident (i.e. that a dispensing error has led to clinical condition x, y and z).
- Where it is unclear whether there is cause for a complaint or if a mistake has been made:
  - I'm sorry that you are upset.
- Where you are satisfied that there is cause for the complaint or a mistake has been made:
  - I am sorry that you have cause for complaint, or I am sorry that we have made a mistake.

30. Review and Notification of Standard Operating Procedures

30.1 Objective

To ensure SOPs are reviewed and improved in a timely manner and following any changes in the Pharmacy workflow, staffing level, volume of dispensing and following any serious incidents or events that are an outcome of any Clinical Governance audits for safer working environments.

30.2 Scope

This SOP applies to the working SOPs relevant to this Pharmacy only.

30.3 Responsibility

It is the responsibility of all staff who work in the Pharmacy to report to the Responsible Pharmacist any incidents/events or near misses a soon as possible to enable the RP to assess, report and take action to avoid reoccurrences. It is the responsibility of the RP to report any changes required to the SOPs and for the overall responsibility of the Superintendent Pharmacist to approve and implement changes to the SOPs.

30.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

30.5 Process

30.6 Reviewing the SOPs (RP)

- Each SOP should be reviewed at least once every two years or
  - following any event that may affect patient safety
  - when new legislation or guidance is introduced which affects what needs to be included within a certain SOP.
- Read carefully through the SOP.
- Identify if there are any sections which need updating.
- If there are no changes necessary and the SOP remains fit for purpose then mark the review box with a signature and date to indicate that the SOP has been reviewed.
- Record on the SOP the date for the next scheduled review – this should be a maximum of two years from the current review date.

30.7 Changing the SOPs (RP)

- Keep existing paper versions of SOPs for 15 years from the date they were last effective and keep copies of electronic SOPs indefinitely.
- Mark the existing SOP to indicate that they are no longer in effect.
- In a new copy of the SOP make any amendments or updates which are necessary to ensure that the SOP remains fit for purpose – be careful that any amendments will not result in a breach of the law or any existing good practice requirements.

- Mark the new SOP to indicate:
  - Date of preparation.
  - The name of the person establishing the new SOPs.
  - The signature of the person establishing the new SOPs.
- Apply a new progressive version number for the new SOP.
- Arrange for pharmacy staff to read the SOP and to sign and date the SOP record sheet.
- Notify the superintendent pharmacist or a person in a position of authority of the review and any consequential changes to the pharmacy procedure, as soon as is reasonably practicable, by completing the 'SOPs Amendment Form' in Appendix 1.

30.8 Notification of the SOPs (RP)

- Inform all relevant staff of any new SOPs or amendments to existing SOPs.
- Ensure that all SOPs are readily available within the pharmacy premises for consultation by pharmacy staff.
- Make arrangements to ensure that all pharmacy staff including occasional staff have read and understood the SOPs applicable to their work and that they have signed and dated the SOP record sheet.
- Signpost new pharmacy staff and casual staff (including locums) to the location of the SOPs within the pharmacy and ensure that they have read and understood the SOPs applicable to their work and that they have signed and dated the SOP record sheet.

30.9 Temporary amendments and deviation from the SOPs (RP)

*Responsible Pharmacist or nominated advisory pharmacist**

The nominated advisory pharmacist is the pharmacist who is available to provide advice and available to be contacted in the absence of the responsible pharmacist.

- In exceptional circumstances where it would be impossible or professionally inappropriate to conform with the procedures outlined in a SOP the pharmacy may temporarily deviate from the procedure without following the formal procedures outlined in the points above.
- Any temporary amendment must be authorised by:
  - The Responsible Pharmacist on duty (whether present or officially absent from the pharmacy premises).
  - The nominated pharmacist providing advice to the pharmacy team in the absence of the Responsible Pharmacist.
- The pharmacist authorising the amendments is professionally responsible for the amendments and must ensure that:
  - Any amendments comply with legal and professional requirements.
  - the procedure is signed and dated to indicate it is subject to temporary amendment.
  - the reason for the temporary amendment is recorded.
- The temporary changes must be communicated to appropriate members of the pharmacy team and, if not authorised by the Responsible Pharmacist, then to the Responsible Pharmacist upon return to the pharmacy.
- Following the resolution of the exceptional circumstance then the SOPs revert back to their original constitution.
- Consider the need for a formal review of SOPs following procedure above.

31. The Responsible Pharmacist

The Health Act 2006 requires by law that every registered Pharmacy premises has a Responsible Pharmacist (RP) in charge to operate and that the supply of medicines must be made either by or under the direct supervision of a registered pharmacist.

31.1 Objective

That the Pharmacy and Pharmacist is compliant with legislation and abides by the regulations governing RP duties and that staff are aware also of the implications of RP presence and even absence from the Pharmacy Premises.

31.2 Scope

This SOP covers the implications of RP presence and absence from this registered pharmacy premises.

31.3 Responsibility

The Dispensers, Delivery Drivers, Technicians, Pharmacists and Responsible Pharmacist and Superintendent Pharmacist.

31.4 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

31.5 Process

- The RP must be fully aware of the limitations on face to face contact that must be adhered to by this Distance Selling Pharmacy.
- The RP has a statutory duty to make sure SOPs are in place that allows the safe and effective running of a pharmacy. These procedures must be maintained and reviewed regularly.
- The RP must make an accurate contemporaneous record showing that they are the RP of a pharmacy for a particular day and time.
- In certain situations the RP may need to be absent from the pharmacy to carry out their work. In this case they would still be the RP of the pharmacy however they will need to follow the guidance relating to absence of the RP. Another pharmacist must always be present if the RP is going to leave the premises for any reason.
- The RP must display a notice stating their name, GPhC registration number and a statement to show they are the RP at that pharmacy at that time.

31.6 Start of shift procedures

- Clearly display your RP notice as detailed above.
- Make sure the Pharmacy RP Record is up to date and check for any absences in the past 24 hours.
- Make an entry into the Pharmacy RP Record including your name, GPhC registration number and the date and time you are taking on the RP duties.

- Make sure you are satisfied that the pharmacy SOPs cover the legal requirements to run the pharmacy safely and effectively and you have read, understood and signed all relevant procedures.
- Check for any notes or messages from the previous RP and contact them if there are any outstanding issues that need resolving.

31.7 End of shift procedures

You should stop being the RP if:

- Another pharmacist is going to assume the duties of RP immediately after you.
- The pharmacy is shutting at the end of the day and no further activities will require supervision by a pharmacist.
- You no longer feel able to undertake the duties of RP in the pharmacy. In this case you should contact the Pharmacy Superintendent immediately.

31.8 Remove the RP notice from display

Leave any notes or messages for the next RP and contact them if there are any outstanding issues that need resolving. If the pharmacy is not closing and the next pharmacist is not immediately available to take up the duties of RP, the current RP should remain at the premises until another pharmacist can assume the duties of RP and the Pharmacy Superintendent should be contacted.

Make an entry into the Pharmacy RP Record showing the date and time you ceased to be the RP.

31.9 Absence of the RP

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) **unless another pharmacist is present.**

The Pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break (as per Working Time Directive) then the second pharmacist must sign in as the RP.

32. Preparing for the absence of the RP

- Ensure the 2nd Pharmacist is aware of your leaving and the length of time you will be absent for.
- Check the Pharmacy RP Record and calculate the maximum amount of time that the RP can be absent from the pharmacy.
- Continue to clearly display your RP notice.
- Make an entry into the Pharmacy RP Record to show the date and time your absence started and the reason for your absence.
- Inform the pharmacy team what time you expect to return to the pharmacy and how they can contact you in your absence.
- The RP should be able to return with reasonable promptness and remain contactable by the pharmacy team during their absence or arrange for another nominated pharmacist to provide advice in their absence.
- The pharmacy team must be instructed that in the absence of a RP the second pharmacist is responsible for the operation of the pharmacy

32.1 During the absence of the RP

- All of the pharmacy team must adhere to the pharmacy procedures set down by the RP.
- Monitor the time that the RP has been absent.
- If the absence exceeds 2 hours:
  - The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty.
  - The pharmacy must contact the RP for additional instructions and the estimated time of return.

32.2 Roles and responsibilities

32.3 Pharmacy Superintendent

- Professionally accountable for all pharmaceutical aspects of the business.
- Sets the overarching standards and policies for the provision of pharmacy standards within the business.

32.4 Responsible Pharmacist

- Must ensure the safe and effective running of the pharmacy for which they are appointed RP.
- Responsible for the processes governing the dispensing, selling and supplying of medicines.
- Responsible for ensuring that appropriate SOPs are in place and are being reviewed when required.
- Must ensure that the standards and policies set by the Pharmacy Superintendent are implemented and amended where necessary.
- Must ensure the role is within their professional competence.
- Must comply with the RP regulations
- Remains subject to the directions of the Pharmacy Superintendent.
- Must personally supervise the sale and supply of all medicines

32.5 Known Risks

- Unforeseen circumstances leading to sudden and immediate loss of the Responsible Pharmacist on duty.

			Receiving a prescription in the post or collected from surgeries	Labelling and assembling of a prescription	Handing dispensed prescriptions to delivery driver
RP present			Y	Y	Y
RP absent up to 2 hrs. – 2nd pharmacist present			Y	Y	Y
RP absent: more than 2 hrs.- 2nd pharmacist becomes RP			Y	Y	Y

Initial Checks
Are all members of the team present?
Are the computer systems working properly?
Are you aware of messages left by the previous RP?

Display Notice
Have you displayed your RP notice and entered your presence on the website admin panel?

Records
Have you completed the Legal RP Record?

Procedures
Have you located the pharmacy SOPs?
Do the SOPs cover the legal requirements needed to operate the pharmacy safely and legally?
Do the SOPs need to be reviewed or amended?
Have you informed the pharmacy team how to contact the Superintendent Pharmacist if you are not contactable?
Are the pharmacy team aware of the procedures which must be followed in your absence?

Miscellaneous
CD keys must be under the personal control of the Pharmacists – Confirm
Have you checked the fridge temperature and log?

33. Repeat Dispensing

33.1 Background

Repeat dispensing is designed to make it easier for patients that receive regular repeat medication that are stable on their medication.

33.2 Repeat Dispensing

Repeat Dispensing is a process by which patients are able to obtain repeat medicines without the need to contact their GP on each occasion. The supplies of medicines are managed by the patient's pharmacy of choice and the patient or representative must visit the same pharmacy for each supply under the service.

The prescriber produces a master 'repeatable' authorising prescription (annotated with RA) on a standard FP10 form and a set of identical 'batch' prescriptions on a standard FP10 form (annotated with RD).
Both forms must be computer generated. Any handwritten amendments, including any additional medication added will invalidate the prescription.

33.3 The Authorising Form

The authorising form (RA) is the legally valid prescription and will give details of how many instalment the prescription contains. The standard expiry of an authorising prescription is one year from the date it was generated.

33.4 The Batch Form

The batch prescription (RD) is not a legal prescription and will not be signed by the prescriber. The RD enables the pharmacy to receive payment for the service under the directions of the authorising prescription. The prescriber's signature box is annotated with the number of the batch, e.g. 'repeat dispensing: 6 of 12'. The date on which the repeats were authorised is printed on all the batch issues.

33.5 Objectives

- To provide a framework for a safe on going repeat dispensing service which includes prompt attention to medication change or any other known changes in patient need.
- To promote the service to relevant patients
- To ensure that the master repeatable prescription and batch issues are stored safely.
- To ensure there is an effective audit trail for each master repeatable prescription and its associated batch issues.
- To ensure that all regular dispensary staff are appropriately trained in accordance with the local PCO arrangements, and that all part-time pharmacists, relief pharmacists and locum pharmacists who work in the pharmacy have also received appropriate training.
- To meet the legal requirements of the Repeat Dispensing service
- To offer a safe and effective service to patients without face to face contact
- Ensure that patients gain maximum benefit from their medication and reduce wastage of medicines.

33.6 Scope

This SOP looks at the procedure involved in processing NHS Repeat Dispensing of Prescriptions and is intended to support the training provided by the CPPE course on Repeat Dispensing.

33.7 Responsibility

The Dispensers, Delivery Drivers, Technicians, Pharmacists and Responsible Pharmacist and Superintendent Pharmacist.

33.8 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

33.9 Process

33.10 Prescription Reception

Appropriate advice about the benefits of repeat dispensing must be given to any patient who:

- has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,
- requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.

- Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them.
- The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.
- Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card.
- When a RA is accepted the details should be checked thoroughly to ensure that there are no omissions or errors which could prevent the dispensing of all the batch prescriptions.
- The RA should be retained in the pharmacy although it is the patient's choice whether they leave the RD with the pharmacy or retain them.

33.11 Pharmaceutical & Legal Assessment

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

- They are taking or using, and likely to continue to take or use the medicine or appliances appropriately
- Advise the patient that they should only order items that they need
- Check that the patient is not suffering any side effects which may suggest they need a review of their medication
- Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.
- Check that there has not been any change to the patient's health since prescription was authorised
- Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form which must be shared with the patient's GP.

The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval.

The dispensing interval does not have to be set by the prescriber; however they may choose to specify one. Unless a specific prescribing interval is specified by the prescriber, it is up to the Pharmacist to use their professional judgement when to dispense the next supply for the patient. The pharmacist must be satisfied that the supply of medicines is clinically appropriate. All medicines may be prescribed under the Repeat Dispensing arrangement except Schedule 1, 2 & 3 controlled drugs. Temazepam and Phenobarbital cannot be prescribed. Other Schedule 4 Controlled Drugs may be prescribed, however the first dispensing must be within 28 days of the appropriate date

Refer to additional SOPs for further guidance on dispensing procedures.

When the last RD is dispensed, a note should be attached to the delivery note to advise the patient that a new repeatable prescription and batch issues will be required for further supplies. If required instruct patient to visit GP for another RA and RDs.

33.12 Practice Guidance

Once a repeatable prescription has been issued, patients taking part must obtain the entire period of treatment included on their prescriptions from the same pharmacy.

The use of repeat dispensing by patients is voluntary and with agreement with their prescriber, patients can choose to use their existing method of obtaining repeat prescriptions or repeat dispensing. Due to the exchange of information about medication between the prescriber and the pharmacy, the patient must give consent before participating in this service. This safeguards the patient's information and complies with current guidelines on data protection. The patient's agreement is recorded on the appropriate form by sending by e-mail to the patient and retaining a record in the pharmacy of their completed form.

33.13 Prescription Filing

The filing box should be checked on a monthly basis and any RAs where the expiry date has been reached prior to all RDs being dispensed should be forwarded to the Prescription Pricing Division (PPD), at the end of the month. Any remaining RDs should be returned to the prescriber.

33.14 End of Month Procedure

Items dispensed within the repeat dispensing scheme should be included within your Prescription Collection Service (PCS) figures when reported on the month end documentation.

All processed RD prescriptions must be submitted to the PPD for payment as part of the normal end of month procedure.

The RA must be submitted to the PPD once all RDs have either been dispensed or expired or the medication is no longer required.

The pharmacy copy of the Customer Record Card should be crossed through and the date that the repeatable prescription was sent to the PPD and number of batch issues remaining detailed in the comments column.

Any information relating to items not dispensed should be recorded in the comments section of the pharmacy record card.

33.15 Repeat EPS Dispensing[4]

When a prescriber issues an electronic prescription for repeat dispensing using their EPS Release 2 prescribing system, in addition to the information found on a standard EPS Release 2 prescription, this electronic repeatable prescription contains:

- the intended interval between each issue of the repeatable prescription
- how many times the repeatable prescription can be issued

Any patient suitable for a repeat prescription could be suitable for electronic repeat dispensing.

This includes but is not limited to:

- Patients on stable therapy
- Patients with long term conditions
- Patients on multiple therapy e.g. hypertension, diabetes, asthma etc.
- Patients that can appropriately self-manage seasonal conditions.

Whilst all the above patient groups are suitable for electronic repeat dispensing the additional functionality allows the patient suitability to be broadened based upon clinical assessment.

33.16 How do you produce an electronic repeat dispensing prescription?

Producing an electronic repeat dispensing prescription is very similar to producing a normal EPS Release 2 prescription.

In some systems this involves an upfront choice to produce an electronic repeat dispensing prescription. Different systems may use different wordings, for example:

- Electronic repeat dispensing
- Batch prescribing
- Repeatable prescriptions

In other systems the prescription items are chosen first and the prescription type is then set as repeat dispensing template. Please see your prescribing systems' training manual for specific details.

[4] https://www.england.nhs.uk/digitaltechnology/wp-content/uploads/sites/31/2015/06/electronic-repeat-dispensing-guidance.pdf

An electronic repeat dispensing prescription can contain up to four items, the same number as on a normal EPS Release 2 or FP10 prescription. Multiple electronic repeat dispensing prescriptions can be issued.

All the items on an electronic repeat dispensing prescription must be in the dictionary of medicines and devices (dm+d) to be suitable for electronic prescribing. This is the same as a normal EPS Release 2 prescription.

An example of good practice for electronic repeat dispensing is to include messages to the patient and dispenser within the electronic prescription to remind them there is no need to reorder the prescription at the prescribing site until the end of the electronic repeat dispensing prescription. For example: Please collect your prescription every 28 days from your nominated pharmacy, there is no need to reorder from your GP until the final issue has been fulfilled.

33.17 What is a repeat authorisation token?

A repeat authorisation token is a master copy of the prescription.

As well as the standard information found on all tokens, such as patient demographics and prescriber details, a repeat authorisation token states:

- items;
- number of issues;
- interval; and
- end date.

This is usually held by either the patient or the dispenser.

A repeat authorisation token can be issued by the prescribing site if the patient requires a copy of their prescription. This allows the patient to attend an alternative dispensing site to collect an issue without changing their nomination or requesting a copy from the prescribing site, and provides information on what has been prescribed and the number of issues. The dispenser does not require the paper repeat authorisation token to dispense or claim a repeat dispensing issue.

33.18 Do I need to issue a Repeat Authorisation Token?

No, the mandatory repeat authorisation token, given to the patient at the start of a repeat dispensing prescription, is optional when issuing a repeat dispensing prescription in the Electronic Prescription Service. If the patient requests a copy of the repeat authorisation token, then the prescriber can issue one at the time of prescribing or at a date in the future within the duration of the prescription. Until system suppliers have made functional changes to their systems, the repeat authorisation token may continue to default to printing, but after 1 November 2014 it will be optional to send this to the patient.

34. Information Governance

34.1 Scope

Systems and procedures that process personal data of individuals including the PMR system. See GPhC guidance on confidentiality for more information.

34.2 Objective

This SOP will ensure that The Pharmacy complies with relevant guidelines and the law concerning Data Protection and confidentiality.

34.3 Risks

- Personal data is revealed without patient consent.
- Personal data is not properly acquired, stored, or maintained.
- Data is not properly protected

34.4 Applicable to:

- Dispensing Assistants.
- Dispensing Technicians.
- Accuracy Checking Technicians.
- Pharmacists.
- All other colleagues.

34.5 Responsible:

- Pharmacists.
- Pharmacy Superintendent.

34.6 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

34.7 Confidentiality

You must respect and protect people's dignity and privacy.

- Take all reasonable steps to prevent accidental disclosure or unauthorised access to confidential information. Never disclose confidential information without consent unless required to do so by the law or in exceptional circumstances.
- You must use information you obtain in the course of your professional practice only for the purposes you were given it, or where the law says you can.
- You must make sure you provide the appropriate levels of privacy for patient consultations. This applies even though we are contacting patients in a non face to face way.

34.8 Data Protection

The PSNC has published detailed guidance on its website which should be referred to along with this SOP in the first instance for data protection queries.

Legal framework governing the processing of Personal Data

The current data protection legislation in the United Kingdom is the Data Protection Act 1998 (the "**Act**"), and with effect from 25 May 2018, will implement the General Data Protection Regulations ("**GDPR**") (for so long as the GDPR is in effect in the United Kingdom) and any successor legislation to the Act and the GDPR, specifically the Data Protection Bill once it becomes law (together the "**Data Protection Laws**"). The Data Protection Laws govern the processing of Personal Data (as defined in the Data Protection Laws). Staff must complete any mandatory training issued from time to time relating to information security, data protection and/or the General Data Protection Regulations.

Key definitions

"Personal data" is any information relating to an identifiable person who can be directly or indirectly identified in particular by reference to an identifier.

"Special categories of data" includes genetic data, health data, and biometric data where that data is processed to uniquely identify a customer.

"Processing" means any operation or set of operations which is performed on Personal Data or sets of Personal Data. This includes, but is not limited to, the collection, recording, organisation, storage, alteration, adaptation, retrieval, use, consultation, dissemination, or otherwise making available of Personal Data.

In relation to a customer's Personal Data, you should comply with the following (where applicable):

1. **You must process the Personal Data lawfully, fairly and in a transparent manner**
   The pharmacy practice leaflet is available on the website and a copy of the leaflet can be sent to customers upon request. The leaflet contains a data protection statement which explains to the customer who is processing their Personal Data and the purposes for which their Personal Data will be processed.

2. **Only collect Personal Data for specified, explicit and legitimate purposes and do not further process the Personal Data in a manner that is incompatible with the original purpose(s) for which it was collected**

   You should only use the customer's Personal Data for the purpose for which it was originally provided and for no other purposes. The Personal Data should be adequate, relevant and limited to what is necessary in relation to the purposes for which it is processed
   You should only access a customer's Personal Data if you have a need to do so, and even then, you should only do so to the extent necessary to achieve the relevant purpose.

   Do not record and/or store Personal Data that you do not need.

   Data should be anonymized where possible.

3. **The Personal Data should be accurate and, where necessary, kept up to date**
   Every reasonable step must be taken to ensure that Personal Data that is inaccurate, taking into account the purposes for which that Personal Data is processed, is erased or rectified without delay.

   You should ensure that you record a customer's Personal Data accurately. When contacting a customer using the Personal Data that they have provided you should confirm that their details are accurate.

4. **The Personal Data should be kept in a form which permits identification of customers for no longer than is necessary for the purposes for which the Personal Data is processed**
   Customer records should not be kept for longer than is necessary.

The relevant retention periods are set out on the GPhC website.

5. **Personal Data should be processed in a manner that ensures appropriate security of the Personal Data, including protection against unauthorised and unlawful processing and against accidental loss, destruction or damage, using appropriate technical and organisational measures**

Personal Data should be protected against unauthorised or unlawful processing and against accidental loss, destruction or damage.

Data Security in the Pharmacy

The patient medication record ("**PMR**") system should only be accessed by a registered Pharmacist (or colleagues under his or her direct supervision who require access).

All staff must log into the PMR system using a specific ID number and password. You must not allow unauthorised colleagues (e.g. non-dispensing staff) to access the PMR system. The password for accessing the pharmacy system should be changed on a regular basis and should not be easy to guess (e.g. it should not be a pharmacist's date of birth).

You must ensure that the log-in terminal for the PMR system is located in an area of the pharmacy that cannot be accessed by anybody other than authorised persons and that the screen cannot be viewed by anybody other than the authorised persons. You should ensure that you make appropriate use of a password-protected screen-saver to prevent others being able to view customer information and you should clear customer information from the screen before accessing another patient's medical record.

All manual files relating to customers of the pharmacy should be kept in a secure location at the pharmacy under lock and key when unattended and keys should be held in a secure place.

When collecting health data from a customer over the telephone, you should be aware that you may be overheard and if necessary take additional steps to protect the customer's privacy, for example, by taking the conversation into a separate consultation room, where available (or at least out of earshot of other colleagues).

All pharmacy customer Personal Data is confidential and must not be disclosed to any other colleague(s) not involved with the customer's care.

If a third party service provider may have access to customer Personal Data (e.g. in the case of a third party that is providing maintenance services in respect of the internal pharmacy system), you should first of all refer the matter to the Superintendent Pharmacist – a contract should always be in place with the third party, that contains adequate data protection provisions to ensure that customer Personal Data is protected. This will usually be in the form of a master agreement or a data processing agreement.

When disposing of confidential information (including spare dispensing labels) and/or customer Personal Data, you need to do so in such a manner that the customer can no longer be identified, for example, by shredding it.

You should not send customer Personal Data by fax.

Disclosing Customer Data

Customer Personal Data is confidential and, at no point, should it be disclosed other than as permitted by the data protection statement in the pharmacy practice leaflet and/or with the customer's express (usually written) consent which must be given prior to the disclosure being made. In the event a customer provides their consent to you verbally, you must keep a record of the consent provided, detailing who provided the consent, why they provided their consent, how they provided their consent and when they provided their consent.

If you are not sure whether you have the customer's consent to share their information for a particular purpose, or the purpose is not specified in the pharmacy practice leaflet, you should

contact the customer and obtain their consent. You should keep a record of their consent (if it is provided). If the customer does not provide their consent, then you should not process their Personal Data for that purpose.

If you believe there is another lawful basis for processing the customer's Personal Data, other than consent, you should reach out to the Data Protection Officer.

The GDPR introduces enhanced rights for individuals. These are set out below with instructions on how to deal with a request from an individual to exercise any of these rights.

Right to be informed

Customers have a right to be informed about the collection and use of their Personal Data, at the time at which their data is collected. You must provide the customer with information including: the purposes for the processing of their Personal Data, retention periods of their Personal Data and who their Personal Data will be shared with. Any new uses of a customer's Personal Data must be brought to their attention. If the customer already has this information, then you do not need to provide it to them again.

Right of access

Customers have a right to access the Personal Data held about them and supplementary information. This right allows customers to be made aware of and to verify the lawfulness of the processing of their Personal Data. Customers have the right to obtain:

- Confirmation that their Personal Data is being processed;
- Access to their Personal Data; and
- Other supplementary information

You should not charge the customer to respond to such requests, although a reasonable fee can be charged where the request is manifestly unfounded or excessive (e.g. if it is repetitive). You may also charge a fee to respond to requests for further copies of the same information. Any fee must be based on the administrative cost of providing the information.

You should verify the identity of the customer that is making the request, using 'reasonable means'. If the request has been made electronically, you should provide the information in a commonly used electronic format.

A request from a customer should be made in writing (email is acceptable). The customer does not have to provide you with a reason for requesting the information. You should log the request on the PMR system.

You or the Superintendent Pharmacist must also notify the Data Protection Officer of the subject access request as soon as it is received.

Subject access requests must be responded to without delay and at the latest within one (1) month of receipt. Where the request is particularly complex or there are numerous requests from the customer, this time frame may be extended by a further two (2) months, but the customer should be informed of the extension (including reasons) within one (1) month.

Any request that is made by a third party for information relating to a customer should be referred to the Superintendent Pharmacist, and notified to the Data Protection Officer as soon as the request is received.

The pharmacy may receive a request from a third party for access to a deceased customer's records. You should refer all such requests to the Superintendent Pharmacist, and notify the Data Protection Officer as soon as the request is received.

Right to rectification

Customers have a right to have inaccurate information held by the pharmacy corrected, or, completed if it is incomplete. Inaccurate information is information which is incorrect or misleading as to any matter of fact. You can accept such requests verbally or in writing.

You should take reasonable steps to satisfy yourself that the Personal Data held by the pharmacy is accurate and to rectify the Personal Data if necessary. You should take into account any information provided by the customer. A record of the mistake should be kept with the rest of the customer's Personal Data.

It is good practice to restrict the processing of the customer's Personal Data whilst the accuracy of their Personal Data is being checked.

If you are satisfied that the data is accurate, then you should inform the customer and let them know that the data will not be amended.

If we have disclosed the customer's Personal Data to others, then we must contact each recipient and inform them of the rectification or completion of the customer's Personal Data, unless this proves impossible or involves disproportionate effort. If we are asked, we must also tell the customer about these recipients.

Always refer such requests to the Superintendent Pharmacist as soon as they are received from a data subject.

Right to erasure

This is otherwise known as the "right to be forgotten".

Customers may make a request to have any Personal Data that we hold on them deleted. They may make the request verbally or in writing. You must deal with such requests promptly and within one (1) month from receipt.

Customers have the right to have their personal data erased if:

•the Personal Data is no longer necessary for the purpose which it was originally collected or processed;

•we are relying on consent as our lawful basis for holding the Personal Data, and the customer withdraws their consent;

•we are relying on legitimate interests as our basis for processing, the customer objects to the processing of their Personal Data, and there is no overriding legitimate interest to continue the processing;

•we are processing the Personal Data for direct marketing purposes and the customer objects to that processing;

•we have processed the Personal Data unlawfully (i.e. in breach of the lawfulness requirement of the 1st principle);

•we have to do it to comply with a legal obligation; or

You should tell other organisations about the erasure of Personal Data, if the customer's Personal Data has been disclosed to them.

The right to erasure does not apply if the processing is necessary for one of the following reasons:

•to exercise the right of freedom of expression and information;

•to comply with a legal obligation;

•for the performance of a task carried out in the public interest or in the exercise of official authority;

•for archiving purposes in the public interest, scientific research, historical research or statistical purposes where erasure is likely to render impossible or seriously impair the achievement of that processing; or

•for the establishment, exercise or defence of legal claims

The right to erasure will not apply to special category data:

•if the processing is necessary for public health purposes in the public interest (e.g. ensuring high standards of quality and safety of health care and of medicinal products or medical devices); or

•if the processing is necessary for the purposes of preventative or occupational medicine (e.g. where the processing is necessary for the working capacity of an employee; for medical diagnosis; for the provision of health or social care; or for the management of health or social care systems or services). This only applies where the data is being processed by or under the responsibility of a professional subject to a legal obligation of professional secrecy (e.g. a health professional).

You should refer such requests to the Superintendent Pharmacist as soon as they are received.

Right to restrict processing

Customers have the right to request the restriction or suppression of their Personal Data in certain circumstances (where they have a particular reason for wanting the restriction). When processing is restricted, you are permitted to store the Personal Data but you may not use it. The customer can make the request verbally or in writing.

Customers have the right to request that we restrict the processing of their Personal Data in the following circumstances:

•where the customer contests the accuracy of their Personal Data and you are verifying the accuracy of the Personal Data;

•the Personal Data has been unlawfully processed (i.e. in breach of the lawfulness requirement of the first principle of the GDPR) and the customer opposes erasure and requests restriction instead;

•we no longer need the Personal Data but the customer needs us to keep it in order to establish, exercise or defend a legal claim; or

•the customer has objected to us processing their Personal Data (where the grounds for processing are in the public interest and/or legitimate interests), and we are considering whether our legitimate grounds override those of the customer.

You must not process the restricted data in any way except to store it unless:

•you have the customer's consent;

•it is for the establishment, exercise or defence of legal claims;

•it is for the protection of the rights of another person (natural or legal); or

•it is for reasons of important public interest.

If the Personal Data has been disclosed to other organisations, then we should notify each recipient of the restriction of the Personal Data unless this proves impossible or involves disproportionate effort. If asked, you must inform the customer about these recipients.

In many cases the restriction of processing is only temporary. If you lift the restriction, you must inform the customer before you lift the restriction.

You must refer any such requests to the Superintendent Pharmacist.

Right to data portability

Customers are entitled to obtain and reuse their Personal Data for their own purposes across different services. This will only apply where we are the controller of the data, and where the processing is based on consent or, for the performance of a contract and where processing is carried out by automated means.

You must provide the Personal Data in a structured, commonly used and machine readable form. Open formats include CSV files. Machine readable means that the information is structured so that software can extract specific elements of the data. This enables other organisations to use the data.

The information must be provided free of charge.

If the customer requests it, you may be required to transmit the data directly to another organisation if this is technically feasible.

You should refer such requests to the Superintendent Pharmacist.

Right to object

Customers have the right to object to:

•processing based on legitimate interests or the performance of a task in the public interest/exercise of official authority (including profiling);

•direct marketing (including profiling); and

•processing for purposes of scientific/historical research and statistics.

You should ensure that such objection is recorded on the PMR and actioned. Always refer such requests to the Superintendent Pharmacist.

If a customer objects to their Personal Data being processed for a particular purpose, you should carefully explain the implications of objecting (including, if applicable, being unable to dispense their prescription) and record such objection. You should not force the customer into providing their consent

Response times

All requests from a customer should be responded to without delay and at the latest within one (1) month of receipt. Where the request is particularly complex or there are numerous requests from the customer, this time frame may be extended by a further two (2) months, but the customer should be informed of the extension (including reasons) within one (1) month. You should discuss with the Superintendent Pharmacist and/or the Data Protection Officer before extending the time frame to respond to a request, as there may be other considerations that need to be taken into account.

Where the customer has made a request for rectification of their Personal Data, erasure of their Personal Data, a restriction on processing, or data portability, and you refuse the request you must explain the reasons for your decision and inform them of their right to make a complaint to the Information Commissioner's Office ("**ICO**") to enforce their rights through a judicial remedy. A record should be kept on our internal system(s) of the customer's request regarding their Personal Data.

If you refuse to deal with a request for rectification, erasure or a restriction on processing because the request is manifestly unfounded or excessive, you will be required to justify your decision to the customer and/or you can charge a "reasonable fee" to deal with the request. You must explain the reasons for your decision and inform them of their right to make a complaint to the ICO to enforce their rights through a judicial remedy if you request a reasonable fee and/or additional information to identify the customer.

Before rejecting a request, you should discuss with the Superintendent Pharmacist and/or the Data Protection Officer, as there may be other considerations that need to be taken into account.

Personal data breaches

All Personal Data breaches must be notified to the Superintendent Pharmacist and the Data Protection Officer as soon as you become aware of a breach or suspected breach, as there are time limits within which the ICO must be notified. You should provide the Superintendent Pharmacist and the Data Protection Officer with all relevant information and all assistance required in connection with a breach or suspected breach. You should not take any steps yourself to notify customers or the ICO.

35. Dealing with Drug Alerts and Recalls

35.1 Objectives

The aim of this SOP is to create:

- An effective procedure for dealing with Drug Alerts and Recalls.
- To ensure best practices are abided by.
- To ensure that stock subject to a recall is not dispensed to patients or sold in the pharmacy.

35.2 Risks

- The subject stock may still be used in the pharmacy.
- Patients may have already received subject stock.

35.3 Scope

This SOP deals with Drug Recalls and Alerts.

35.4 Responsibility

Dispensers, Technicians and Pharmacists.

35.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

35.6 Process

Recalls – Healthcare Professionals' Responsibilities.

MHRA Drug Alerts are distributed via the Department of Health's Central Alerting System (CAS) and the pharmacy and personnel are all registered with access to this service and will receive email alerts via the NHS mail service. CAS is an electronic cascade to Pharmacy Departments in NHS Hospital Trusts via Regional Pharmaceutical Officers, to Private Hospitals via the National Care Standards Commission, to Community Pharmacists, General Practitioners and Dental Surgeons, as appropriate via local Action Teams (IAT's).

Further details regarding CAS can be found at the following link

https://www.cas.dh.gov.uk/Home.aspx

Licence holder led recalls are usually addressed direct to recipients of the affected batch(es), or via notices on delivery notes from wholesale dealers. Whichever form the recall takes, the principals of this section apply.

"What am I supposed to do with the information?"

The Drug Alert will contain an outline of what actions should be taken; this may also be followed up with further details from the licence holder in a subsequent communication. Recipients of recall notices should have in place local procedures that identify the actions that need to be taken in response to each recall notice, whether a DMRC Drug Alert or a licence holder recall.

Instructions within Drug Alerts need to be acted upon appropriately, examples of each class of Drug Alert are given at the end of this SOP

The actions which should be taken are as follows:

1. Read the Alert and identify who it is intended for.

2. Identify the Class of the Alert.

   The timescales specified on Drug Alerts are for advice to give some indication of the priority with which action should be taken.

3. Check if you have had any stock of the affected product using the information provided in the Drug Alert. Each Drug Alert gives distribution dates as well as batch and expiry information. If, based on the information provided, it is unlikely that you have had any of the affected products, you do not need to do anything else, e.g. if you have not had any deliveries since the date of first distribution of the product, you are unlikely to have any stock.

4. If you have stock of the affected product, place this in the specially designated quarantine area and inform all staff about the details of the recall. Stock should also be deducted from the stock levels in the computer system.

   Consider outstanding orders and recent deliveries, these may have been dispatched before the recall notice was issued

5. If you have supplied products for stock to other organisations ensure that they are aware of the recall, e.g. care homes or other organisations or wholesaling to other organisations.

6. For patient level recalls check dispensing records, and identify patients who have received the affected batches.

   If you are not able to identify batch numbers or suppliers from your records you may need to contact every patient who has received the named product since the date of first distribution.

   If a patient level recall is needed, the licence holder may also consider public announcements.

   You may need to be prepared to provide replacement stock for the patient, and may need to make arrangements for new prescriptions; in certain circumstances you may need to consider making an emergency supply (see the current edition of Medicines Ethics and Practice published by the Royal Pharmaceutical Society of Great Britain for further information).

7. If you have problems or queries regarding the recall you should contact the licence holder via the contact details given on the Drug Alert.

8. If you have problems with the quality of the text, or other transmission issues, you should contact the next level of the cascade up from you. You should ensure that you know who this is, e.g. for community pharmacists and GPs this will usually be the local Action Teams.

9. If neither of the above is able to help, you should contact the DMRC.

10. Advice within medicines drug alerts should not override professional judgment in making decisions in the best interest of their patient.

11. The RP involved in cascading or responding to drug recalls should ensure that they fully document any action that they take with regards to a recall.

Note of Drug Alert or Recalls

Drug Alerts have the following classifications:

- Class 1 Action Now (including Out of Hours).
- Class 2 Action within 48 hours.
- Class 3 Action within 5 days.
- Class 4 Caution in use.

Drug Alerts Classes 1 to 3 will be augmented with the words "Medicines Recall" in the title.

An additional classification, "Drug Safety Information" has been introduced for Pharmacovigilance alerts. Drug Safety Information messages should be disseminated immediately upon receipt during working hours to the health professionals specified.

36. Facilitating Remote Access

36.1 Objectives

The aim of this SOP is to create:

- To facilitate and improve remote access to pharmaceutical services for patients

36.2 Risks

- Ensuring that services to be accessed remotely are appropriate for remote access

36.3 Scope

All relevant services

36.4 Responsibility

Superintendent Pharmacist

36.5 Review

The SOP will be reviewed at least once every two years by the Pharmacy Superintendent and changes made to reflect new legislation if appropriate.

The SOP will be reviewed following a critical incident.

An entry should be made into training records for each employee that has read, understood and agreed to follow this Standard Operating Procedure.

36.6 Process

At least every 6 months the SP must

- Review the previous Remote Access Plan
- Consider and relevant changes in technology that could facilitate remote access to pharmaceutical services.
- Review the use of remote access by patients to existing services
- Review feedback from users of the services that have been accessed remotely
- Update the Remote Access Plan to discuss with other pharmacy staff members and the providers of the IT solutions for the pharmacy
- Agree processes and timescales for any changes to remote access
- Produce a communications plan to be sent to patients about proposed changes

37. Pharmacy Staff SOP Acknowledgment and Update Log

NOTE TO PHARMACY TEAM
THIS PAGE SHOULD BE INSERTED AT THE BEGINNING OF EACH SOP AND FILLED IN AND UPDATED AS REQUIRED

Record of SOP Updates and Reviews:

Insert page at the end of each SOP and add extra lines as required

Title of SOP	Update or Review?	Date Carried Out	Carried Out By	Confirm Update Provided to Staff Members	NOTES
1.					
2.					
3.					

I confirm that I have read and understood the following SOP:

Insert page at the end of each SOP and add extra lines as required

Title of SOP	Name	Signature	Position	Date of Completion	RP Authorisation
4.					
5.					
6.					

38. Appendices

38.1 Appendix 1 SOP Amendment Form

SOP Amendment Form

Name of SOP:

Details of Amendment:

Requested From:	**Position:**
Signed:	**Date:**

.....

For Office Use Only

Details of Amendment:

Approved By	**Position:**
Signature:	**Date:**

FULL SOP / GUIDANCE NOTES NOT PROVIDED AS NOT RELEVANT TO REG 25 APPLICATION. CAN BE PROVIDED ON REQUEST

38.2 **Appendix 2 A Guide to Confidentiality**

A Guide to Confidentiality

38.3 **Appendix 3 Pseudoephedrine and Ephedrine**

Pseudoephedrine and Ephedrine:

38.4 **Appendix 4 Daily Delivery Manifest**

Daily Delivery Manifest

To be completed for all deliveries to patient's home or representatives, in order of route.

38.5 **Appendix 5 Controlled Drug Record Sheet**

Controlled Drug Record Sheet

38.6 **Appendix 6 Fridge Temperature Record Chart**

38.7 **Appendix 7 NPA Guidance on Controlled Drugs Legal Requirements**

NPA Guidance on Controlled Drugs Legal Requirements

38.8 **Appendix 8 Controlled Drugs Practical Guidance**

Controlled Drugs - practical guidance

Appendix 9 Record of Destruction of CD Stock

38.9 **Appendix 10 Supply of Methotrexate**

Supply of Methotrexate

Guidance Notes

38.10 **Resources and Other Information**

NPA resources

38.11 **Appendix 11 Supply of Anticoagulants**

Supply of Anticoagulants

38.12 **Child and Vulnerable Adult Protection Policy**

DOCUMENT AMENDMENT HISTORY

Revision No.	Originator of change	Date of change	Change Description

ANY REQUEST OR PROVISION OF ANY NHS ESSENTIAL SERVICE MUST BE DONE **WITHOUT** FACE-TO-FACE CONTACT OR COMMUNICATION WITH ANY PATIENT.

ESSENTIAL SERVICE	**ACTIVITY**	**IDENTIFICATION**	**PROCEDURE**
Dispensing of Medicines	**Sign Up and Nomination**	• Online • Video Conferencing • Telephone • Email • Text Message • Leaflets • Any other non-face to face method of communication.	SEE SOPS
	Contacting the Patient	• Online Chat • Video Conferencing • Telephone • Email • Text Messages • Any other non-face to face method of communication.	SEE SOPS
	Receipt of Prescription	NHS ETP Email Fax + Scans Uploads Surgery Collection Service	SEE SOPS
	Exemption Checking	In house - SOPs	SEE SOPS
	Pharmaceutical + Legal Assessment	In house SOPs	SEE SOPS
	Intervention + Problem solving	In house SOPs	SEE SOPS
	Accuracy Checking	In house SOPs	SEE SOPS
	Owing Management	All communication as detailed above. Patient will be kept informed accordingly.	SEE SOPS
	Emergency Supply	See SOPs.	SEE SOPS
	Bagging Up	In House SOPs	SEE SOPS
	Deliveries	Standard Post Delivery Van Courier Service	SEE SOPS
Electronic Repeat Dispensing		NHS ETP Email Fax + Scans Uploads Surgery Collection Service	SEE SOPS
Appliance Dispensing		NHS ETP Email Fax + Scans Uploads Collection from Surgery	SEE SOPS
Discharge Medicine Review		NHS Mail PharmaOutcomes referrals	SEE SOPS

HALODIRECT

ANY REQUEST OR PROVISION OF ANY NHS ESSENTIAL SERVICE MUST BE DONE **WITHOUT** FACE-TO-FACE CONTACT OR COMMUNICATION WITH ANY PATIENT.

Public Health Campaign		Leaflets in bags Leaflets through 3rd party Online/Website	SEE SOPS
Healthy Living Pharmacy		Leaflets in bags Leaflets through 3rd party Online/Website	SEE SOPS
Selfcare		Leaflets in bags Leaflets through 3rd party Online/Website	SEE SOPS
Sign Posting		• Online • Video Conferencing • Telephone • Email • Text Message Any other non-face to face method of communication.	SEE SOPS
Collection + Disposing of Unwanted Medication		Delivery Driver Appointed mailing service Couriers	SEE SOPS
Referrals		• Online • Video Conferencing • Telephone • Email • Text Message Any other non-face to face method of communication.	SEE SOPS
Incidents		Recorded in National platform	SEE SOPS
Feedback		• Online • Video Conferencing • Telephone • Email • Text Message Any other non-face to face method of communication.	SEE SOPS
Complaints		• Online • Video Conferencing • Telephone • Email • Text Message Any other non-face to face method of communication.	SEE SOPS

How we will involve patients in decisions on pharmacy applications

When we receive an application to move an existing pharmacy or to open a new pharmacy we must write to:

- nearby pharmacies
- in some cases, nearby doctors' surgeries
- the Health & Wellbeing Board which is a committee of the borough, county or city council, and
- the local Healthwatch organisation, which exists to represent local patients in general

We send them a copy of the application and invite them to make comments within 45 days. Comments can be made by letter or email.

In addition, the law requires us to involve patients in our decision-making. We may do this by sending copies of pharmacy applications to:

- city/district and county councillors covering the area involved
- the town or parish council covering the area. In areas which do not have a town or parish council we may instead contact prominent community, neighbourhood or residents' groups
- patient representative groups attached to nearby doctors' surgeries.

They will also be invited to make comments within 45 days.

When we send them a copy of an application we will also send notes to explain:

- what the application is about
- why they are being asked for comments
- what we will consider when making a decision, and
- what happens next after a decision is made.

Applications are not confidential. If they want, councillors or patient groups may share details with local people so they can also make comments within the same 45 day period.

Any comments we receive will be sent to the pharmacy applicant. They will have a chance to respond to us about those comments.

Most applications are decided using written information, including any comments received.

In general, we will not hold public meetings about pharmacy applications. This is because an applicant cannot be made to attend to respond directly to any questions from members of the public.

However, we may hold a hearing if we need more information before making a decision. Where written comments from councillors or patient groups suggest that

local people hold strong views, we will invite those councillors or patient groups to attend the hearing.

The hearing will be held in public so that (although members of the public will not be able to ask questions) they will be able to hear the arguments for and against the application. These will include any comments made by their representatives and the responses received.

All comments at the meeting will be taken into account in making a final decision on the pharmacy application.