2 October 2024

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

REF: SHA/26265

APPEAL AGAINST COVENTRY AND WARWICKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY PRESCRIPTION POINT LTD T/A CARE QUALITY PHARMACY FOR A RELOCATION THAT DOES NOT RESULT IN A SIGNIFICANT CHANGE TO PHARMACEUTICAL SERVICES PROVISION UNDER REGULATION 24 FROM UNIT SF1 LITTLE HEATH INDUSTRIAL ESTATE, OLD CHURCH ROAD, COVENTRY, CV6 7NB TO UNIT 2 BURNSALL ROAD, CANLEY, COVENTRY, CV5 6BS

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Temple Bright LLP on behalf of Prescription Point Ltd t/a Care Quality Pharmacy
PCSE on behalf of Coventry and Warwickshire ICB

NHS Resolution

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1 The Application

By application dated 2 January 2024, Prescription Point Ltd t/a Care Quality Pharmacy ("the Applicant") applied to Coventry and Warwickshire ICB ("the Commissioner") for a relocation that does not result in a significant change to pharmaceutical services provision under Regulation 24 from Unit SF1 Little Heath Industrial Estate, OId Church Road, Coventry, CV6 7NB to Unit 2 Burnsall Road, Canley, Coventry, CV5 6Bs. In support of the application it was stated:

1.1 In response to why the application should not be refused pursuant to Regulation 31, the Applicant stated "n/a".

1.2 In response to "If you are undertaking to provide appliances, specify the appliances that you are undertaking to provide (or write 'none' if the pharmacy does not provide appliances)" the Applicant stated "None".

Information in support of the application

1.3 "We are a DSP so will not have any significant change."

1.4 In response to "Are the services to be provided at the new premises the same as those that have been provided at the current premises (whether or not, in the case of enhanced services NHS England or the relevant delegated integrated care board chooses to commission them)?" the Applicant ticked "Yes".

1.5 In response to "Will there be any interruption to service provision" the Applicant ticked "No".

1.6 In response to "Are you applying for a relocation in relation to distance selling premises?" the Applicant ticked "Yes".

1.7 In response to "In my/our view this application should not be refused pursuant to Regulation 25(2)a)" the Applicant stated "n/a".

1.8 In response to "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.

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

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

1.9 "RP on site at all opening times and available to provide essential services to persons anywhere in England. Supported SOPs in place. Clear communication channels available between patients and staff. Long standing existing pharmacy service. Full compliance to stringent GDPR legislation. Regular contact between patients and service. All consultations carried out remotely with prescription delivery."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 18 June 2024 states:

2.1 "NHS Coventry and Warwickshire ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning."

[Any reference to 'Committee' in this section is not to be confused with the Pharmacy Appeals Committee of NHS Resolution]

2.2 "The Committee have refused the following application for No Significant Change Relocation within a HWB's area.

2.3 Prescription Point Ltd (FCR12)

2.4 Relocation within the same Health & Wellbeing Board Area (Coventry).

2.5 From: Unit SF1, Little Heath Industrial Estate, Old Church Road, Coventry, West Midlands, CV6 7NB

2.6 To: Unit 2, Burnsall Road, Canley, Coventry, CV5 6BS

Determination

2.7 PSRC has refused the application as the applicant has not met the requirements of the regulations listed below pertaining to a Relocation within the same Health and Wellbeing Board area.

2.8 (Regulation 24(3)(d)(ii) and Regulation 25(2)(d)(ii) pertaining to distance selling pharmacy – relocation within the same health and wellbeing board area, as no SOPs have been provided.

2.9 Regulation 24(3)(d)(ii) – Not satisfied

2.10 Although the applicant has stated that they have all relevant SOPs in place, these have not been provided or reviewed recently, therefore no assurance given.

2.11 Regulation 25(2)(d)(ii) – Not satisfied

2.12 The applicant has not provided the assurance of safe and effective provision of essential services."

3 The Appeal

In a letter dated 17 July 2024 addressed to NHS Resolution, Temple Bright LLP on behalf of the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for Prescription Point Limited which is included in the pharmaceutical list for premises trading as Care Quality Pharmacy, Unit SF1 Little Health Industrial Estate, Old Church Road, Coventry, CV5 7NB.

3.2 On behalf of my client I write to appeal a decision of NHS England to refuse my client's application for a no significant change relocation to premises at Unit 2 Burnsall Road, Canley, Coventry, CV5 6BS. The decision was notified to my client by letter dated 18th June 2024.

3.3 By way of background, my client is currently included in the pharmaceutical list for premises at Unit SF1, Little Heath Industrial Estate, providing pharmaceutical services as a distance selling pharmacy ("the Pharmacy").

3.4 The Pharmacy has been providing NHS pharmaceutical services in the distance selling context for several years. It is of note that there has never been any complaint, whether from the NHS or from any patients, regarding the way in which pharmaceutical services are provided by the applicant. In particular, there has never been any concern that the Pharmacy is failing to provide NHS services safely and effectively, without face-to-face contact, to patients anywhere in England throughout the Pharmacy's contractual opening hours.

3.5 In January 2024, my client submitted an application to NHS England to relocate the Pharmacy to new premises in the same HWB's area. The application has been made to allow the Pharmacy to operate from larger premises, as its current premises are too small. The proposed premises have been secured by the applicant and registered with the GPhC.

3.6 As NHS Resolution will be aware, by reason of regulation 24(3)(d), NHS England was required to be satisfied that, if the application had been one to which regulation 25(1) applied, it would not be refused pursuant to regulation 25(2).

3.7 In relation to regulation 25(2)(a), the premises proposed in my client's relocation application are not the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.8 In relation to regulation 25(2)(b), my client's application explained that appropriate procedures were in place to ensure the safe, effective and uninterrupted provision of pharmaceutical services in the distance selling context to patients anywhere in England. Details of those procedures were not requested by NHS England and were not provided, since my client assumed that NHS England would have been satisfied that the pharmacy was operating within the Terms of Service as it has done so for several years without compliant.

3.9 NHS England considered my client's application and refused it, noting that, in NHS England's view, my client had not provided sufficient information to NHS England to satisfy it that the regulatory test was met by the application.

3.10 My client therefore appeals the decision to refuse its application. In support of this appeal, I attach to this letter of appeal a document which summarises how the Pharmacy does (and will at the proposed site) provide each essential services safely and effectively in the distance selling context.

3.11 My client asserts that the information provided within this appeal is sufficient to satisfy NHS Resolution (which is considering the application afresh, rather than as a review of NHS England's decision) that the procedures for the Pharmacy are likely to secure:

3.11.1 The uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who requests those services, and

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

3.12 Whilst my client believes that the attached information [see below] should be sufficient to satisfy NHS Resolution that the relevant regulatory test is met by this application, if NHS Resolution considers that there are any matters that my client has not fully addressed to its satisfaction then NHS Resolution is requested to invite my client to comment specifically on those matters before the appeal is determined.

3.13 On behalf of my client, I therefore invite NHS Resolution to uphold this appeal and to grant my client's application for relocation."

Supporting information included with the appeal:

"Procedures for providing NHS Essential Services remotely for a Distance Selling Pharmacy (DSP)

3.14 NHS Essential Services will be provided to any patient living in England who requires such services, as stated on our website and in our practice leaflets. Any approach to use the pharmacy in person will be refused and a non-face-to-face method will be advised. The pharmacy will explain to the patient that this is in line with our NHS Terms of Service agreement. On all instances the pharmacy must signpost the patient in providing support and ensuring if a face-to-face consultation is required then a local service using NHS Choices can be located. Care Quality Pharmacy provides uninterrupted service provision for the duration of the pharmacy's opening hours and has a full time Responsible Pharmacist in charge of all pharmacy operations and clinical decisions.

Communication Channels

3.15 The pharmacy will use telephone, email, video-conferencing, or other types of non-face-to-face communications including text messages to contact patients. Confidential information will only be given after the patient identity has been verified by confirming the patient name, full address and date of birth. The pharmacy has an online portal that can also be used to provide updates on prescription delivery times as well as secure messaging. Registration services or requests to join the pharmacy are available online and by telephone.

Dispensing

3.16 As per the NHS Terms of Service, there are SOPs in place to ensure safe dispensing services are available to any patient of Care Quality Pharmacy.

3.17 The pharmacy receives prescriptions via the Electronic Prescription Service via nomination with the GP or by using the pharmacy website and app. Patients can also contact the pharmacy by telephone and consent to the pharmacy to nominate the patient. Prescriptions can also be sent to the pharmacy via post and the pharmacy has a pre-paid Royal Mail account.

3.18 When prescriptions come in by post or from collection by the delivery driver they are checked for legal and clinical appropriateness by the Responsible Pharmacist and then

dispensed accurately following SOPs. At this stage, if the pharmacy cannot dispense a prescription the patient is contacted using their preferred contact method. The pharmacy utilises its communication channels to ensure the Responsible Pharmacist can contact the patient for any reason and to ensure there is no obstruction to communicating messages to the patient. All communication is recorded appropriately.

NHS Prescription Charges and Exemptions

3.19 Receiving Hardcopy FP10 NHS prescriptions

3.20 NHS prescription may arrive at the pharmacy in either an electronic form (via ETP) or in hardcopy form via an FP10 (green prescription) through post or delivery driver. In regards to hardcopy, the patient or their representative must complete the relevant sections of the reverse of the FP10DT EPS dispensing token to claim exemption from NHS prescription charge payment & the Pharmacist should check this is completed with the patient / their representative by telephone or by the agreed contact method.

3.21 Electronic checking.

3.22 In accordance with regulation 3(1) or (1A) of the Charges Regulations(1), before providing any drugs or fulfilling a prescription form or a repeatable prescription, our Responsible Pharmacist will determine whether any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified.

3.23 If the patient declares a specific exemption, they will be eligible to receive free NHS prescriptions from our pharmacy. This is checked through Real Time Exemption Checking (RTEC) functionality.

Invalid Exemptions

3.24 In the event, that the patient declares an exemption and the RTEC shows this to be invalid, patients may submit hardcopy proof of exemption to the pharmacy for validation. Document(s) can be sent to the pharmacy for verification via the delivery driver and then later returned to the patient. The PMR system would then 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 (ie for deliveries made other than by the pharmacy’s delivery driver), the patient may scan or email a copy of the evidence to the pharmacy (or use the postal / courier service). This is done by sending it using a pre-paid envelope that can be obtained by post from the pharmacy. The pharmacy can record that the evidence provided was not in the original format. It is the pharmacist in charge who determines if the evidence is satisfactory; if not, they should check the ‘Evidence not Seen’ box. Exemptions sent to the pharmacy by post will have postage paid by the pharmacy, and the exemption will be returned to the patient free of charge.

3.25 The type of exemption and its expiry date will be recorded in the Patient Medication Record (PMR).

3.26 If the patient is not exempt, prescription charges will be processed through a secure online payment method.

3.27 The pharmacy provides a number of options for patients to pay for their prescriptions, including ‘pay-by-link’, BACS transfer or by phone. For local deliveries payment is taken by card or cash if appropriate, by the driver.

Emergency Supplies

3.28 Receiving a Doctor's request for an Emergency Supply.

3.29 When a prescriber (doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, optometrist or pharmacist nurse prescriber) makes a request for medication without a valid prescription by phone, then the pharmacist should speak to the prescriber. A faxed prescription should be authenticated by phone. The prescriber must provide the pharmacy with a valid prescription within 72 hours for the telephoned prescriptions. The pharmacy must supply the prescription-only medication according to the directions and quantity requested by the prescriber.

3.30 Dealing with controlled drugs requests.

3.31 Emergency supply at the request of a prescriber is not allowed for schedule 1, 2 or 3 CDs except phenobarbitone for use in epilepsy.

3.32 Once the pharmacist is satisfied that the supply can occur.

3.33 The medication needs to be dispensed via the PMR, following the procedure for assembling and labelling prescriptions.

Labelling the supply.

3.34 A duplicate set of labels should be generated and stuck into a special emergency supplies book (or the back of a prescription book) to provide an easily accessible record of outstanding prescriptions.

3.35 Upon receipt of the prescription, this record should be marked 'Rx received', with the date of receipt and date on the prescription. The exemption status of the patient should be noted on this record or the number of NHS fees paid. This will enable the correct completion of the back of the prescription when received.

Emergency supply register.

3.36 An entry must be made on the electronic prescription register, which will occur automatically if an entry is made on the correct PMR setting 'emergency supply GP request' or' emailed script' as appropriate. This entry (or a manual record in the prescription book) must state: date of supply, name, quantity, form and strength of medicine, the name and address of the prescriber, the name and address of the patient. When the prescription is received (within 72 hours) the date on the prescription and the date on which the prescription is received should be added to the computer record. A hard copy of these records can be produced using the computer reports function if necessary.

Emailed Prescriptions

3.37 Emailed prescriptions do 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. An emailed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.

3.38 The pharmacist should not dispense against emailed prescriptions and instead should use the Emergency Supply procedures.

Delivery of Urgent Supplies

3.39 Considering the urgency of such requests, the Pharmacy will give priority to delivering the medication to the patient. For local deliveries, the driver will be explicitly notified that the items are "URGENT," and for Royal Mail deliveries, the courier will be instructed to deliver the items as soon as possible via the quickest route available. The Pharmacy will not impose additional fees on the patient, even if incurred during the

delivery process. Apart from acknowledging the urgent nature of the delivery, standard delivery procedures will be followed.

Serious Shortage Protocol (SSP) – Procedure

3.40 Pharmacies are able to manage any serious shortages of medicines with accordance with SSP, without needing to refer patients back to prescribers. Details will be updated above as and when changes occur, but the most up-to-date information is available from the NHS Business Services Authority (NHSBSA) website.

3.41 https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortageprotocols-ssps

3.42 When an SSP has been granted for a product, explain to the patient via telephone or the preferred contact method that due to stock shortages issues the government has allowed the pharmacy to either substitute the product or dispense a reduced quantity and obtain the patient's consent to proceed.

Dispensing Process for Electronic Prescriptions

3.43 Dispense the item with the appropriate product or quantity reduction as described in the SSP following the Assembling and Labelling SOP.

3.44 For prescriptions requiring a smaller quantity than prescribed to be dispensed in accordance with an SSP:

3.45 Create a dispensing label and record for the reduced quantity to be supplied to include free text in the dosage instruction field:

'Supplied under Serious Shortage Protocol (3-digit ref code)'

3.46 For prescriptions requiring an alternative product or strength than prescribed to be dispensed in accordance with an SSP:

3.47 Create a record and label for the actual product being supplied by entering it into the PMR as if the item was prescribed on a paper FP10

3.48 Produce a dispensing label to include free text in the dosage instruction field:

'Supplied under Serious Shortage Protocol (3-digit ref code)'

Dispensing process for paper prescriptions

3.49 Dispense the item with the appropriate product or quantity reduction as described in the SSP following the Assembling and Labelling SOP. Make a record in the PMR of the product being supplied

3.50 Create a dispensing label to include free text in the dosage instruction field:

'Supplied under Serious Shortage Protocol (3-digit ref code)'

3.51 This creates the professional record for the SSP supply

Endorsement

3.52 SSP [followed by the three-digit reference number applicable to the SSP] – to indicate that the supply was made in accordance with an SSP;

3.53 Details of product supplied in accordance with the SSP (drug name, quantity, strength, formulation, supplier name or brand)*;

3.54 Quantity supplied*;

3.55 Pack size – best practice where multiple pack sizes are available; and

3.56 Invoice price – only if NHSBSA has no list-price available on dm+d.

Process for claiming and/or submission

3.57 If the patient is non-age exempt or pays for their prescriptions obtain the appropriate patient declaration in the usual way if supplying an alternative product for the same treatment length

3.58 If the patient is non-exempt and receiving a smaller quantity of the medicine or fewer appliances than the quantity originally ordered on the prescription no prescription charge is payable. The reverse of the prescription will not need to be completed

3.59 If SSP claims are submitted electronically, the Dispense Notification (DN) message should be submitted during the period of SSP validity.

3.60 Any paper prescriptions with SSP claims must be placed in a red separator and dispatched to the relevant division of the NHSBSA by the 5th of the month following that in which supply was made.

3.61 There is a separate declaration of monthly SSP claims on the digital FP34C submission form via the Manage Your Service (MYS) portal for contractors to declare the correct number of SSP claims made each month.

Owings and Out-of-Stock Items

3.62 For medication owings, the pharmacy produces an owings slip informing the patient of the owed quantity. Before sending the medication to the patient the pharmacy calls the patient and confirms they are ok accepting a part supply. If this is not the case the prescription is returned to the patient via EPS back to the NHS Spine or via post if a paper prescription. If the patient agrees to receive the medication, the medication is sent out followed by the owed medication when it is back in stock. At any time when medication is sent out with an owing, an owing slip is always added to the delivery. This clearly identifies the medication and quantity owed by the pharmacy. For medication that becomes out-of-stock and is difficult to obtain, the pharmacy contacts the prescriber if consent to do so has been given or the patient is informed to contact the GP for alternatives.

Counterfeit prescription

3.63 For paper prescriptions received in the post, check for forgeries, especially prescriptions for items such as diazepam, dihydrocodeine, codeine, Oramorph. To confirm the identity and license status of a doctor, check online registers e.g. doctors http://www.gmc-uk.org/doctors/register/LRMP.asp

Blacklisted items.

3.64 Check for NHS blacklisted items (use the Drug Tariff) or drugs requiring 'SLS' or 'OC' endorsements. If unsure whether an item is allowable on FP10, check with the NHS prescription team. Check whether the prescriber is allowed to prescribe the item (see Drug Tariff and BNF for formularies for each type of prescriber for NHS scripts. If any issues are raised then the patient must be contacted by telephone or their preferred contact method and informed of any potential delay to their supply.

Remote Appliance Fitting and Dispensing

3.65 Receiving a Repeat Appliance Prescription

3.66 In the event that a prescription for an appliance which needs fitting is received from a patient, before ordering the medicine, pharmacy staff will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there is no change to the size that is needed.

Receiving a New Appliance Prescription

3.67 In the event that there is a new prescription for an appliance which needs to be fitted, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will inform the patient that the pharmacy complies with the NHS Terms of Service and will;

3.67.1 if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

3.67.2 if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist. In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care.

Dispensing Appliances

3.68 Pharmacy will be dispensing appliances ‘’with reasonable promptness" to patients. Patients should be appropriately advised on the importance of only requesting items they actually need to minimise waste without face-to-face contact. This can be done through telephone, text, email or video call. If the pharmacist is unable to provide appliance states [sic] on prescription, then subject to the consent of the patient, the pharmacist can refer the prescription to another provider electronically for dispensing. If the patient does not consent to the prescription being referred to another provider, the pharmacist must give the patient the contact details of two providers of appliances through telephone, text, email or video call. Home delivery for appliances must be made with reasonable promptness and at a time agreed with the patient. When delivering such appliances, the packaging used for the appliance must not have any markings which could indicate the contents, and the method of delivery must not convey the type of appliance being delivered. Home delivery is made by the pharmacy staff or Royal Mail. Pharmacist must provide a reasonable supply of appropriate supplementary items (disposable wipes and disposal bags). Pharmacist must ensure that the patient can consult a person to obtain expert clinical advice about the appliance. Advice on how to keep or store medications can be provided through telephone, text, email or video call by trained pharmacy staff.

Pharmacy Deliveries

3.69 Pharmacy deliveries are carried out either using a pharmacy driver, Royal Mail or an approved courier partner. Factors such as type of medication and location are considered when selecting the delivery method. For local deliveries we operate within a 30 mile radius.

Local Delivery

3.70 Obtain authorisation of request for delivery

3.71 After gaining online / phone / written consent from the patient update the pharmacy PMR system.

3.72 Dispense items against the prescription and generate three names/address labels. Attach the 1st label to its corresponding bag of medication and store it, with the FP10 prescription attached, in an appropriate place, awaiting collection by the delivery person. Attach the 2nd label to the branch record sheet. Attach the 3rd label to the delivery record book with one label per page.

3.73 Confidentiality is maintained by having one label per page as each delivery recipient is unable to see the personal details of any other. Any information (such as a FRIDGE or CD sticker) should be stuck in the delivery record book on the appropriate page, on the branch record sheet entry and onto the bag of medicine, to alert the patient and also to alert staff if goods are returned to the branch due to delivery failure.

3.74 In the event that there is insufficient medicine stock.

3.75 If there is insufficient medicine to complete a prescription, dispense as much as possible and attach an owing note to the delivery record book, for the driver to give to the patient. Dispense the remainder in the usual way for Owings and phone the patient to arrange a second delivery time for the owing medication (see SOP for Owings).

MDS trays

3.76 These should be sealed in a bag with the bag label attached. Put everything in one bag if possible.

Record the delivery

3.77 Write the number of bags for each person in the delivery record book and branch record sheet.

Driver arrival

3.78 When the driver arrives, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Complete as necessary with fridge and CD items. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the branch record sheet at this stage to confirm the pickup.

Controlled drugs delivery

3.79 If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry. CD’s are always packaged separately from other medication and a CD sticker attached to the bag. The items are placed in a coded locked safe box within the vehicle to keep them secure. Additionally, all vehicles are locked each time the driver leaves. The type of vehicle used is always a van with no rear windows, minimising any potential break in risk.

Driver departure.

3.80 Ensure that the driver takes the delivery record book with them. The branch record sheet stays in the pharmacy as a record of which items have been taken by driver. On delivery at the appropriate address, the driver should give the patient every opportunity to answer the door.

3.81 IF THE PATIENT IS IN:

3.81.1 The driver should state that they are delivering medication from the pharmacy and check the patient's name, address and date of birth as well as confirming if they are expecting a delivery from the pharmacy. The number of packages to be delivered should be confirmed against the entry in the delivery record book.

3.81.2 The patient must sign the delivery record book on receipt of their medication. The driver should not enter the patient's house if possible.

3.81.3 The book must be returned to the pharmacy as proof of delivery before the close of business that day.

3.81.4 The driver should not offer medical advice unless qualified to do so. If the patient has a query about their delivered medication, the driver can provide the telephone number of the pharmacy (which is printed on all medication labels) and ask the patient to phone the pharmacy for advice. If the driver is asked to give written advice to a patient in the form of a note or letter from the pharmacy, then the pharmacy should phone the patient after delivery to ensure the note has been received and understood. Medicines should be kept securely in the vehicle, and doors and windows are closed/locked at all times. The medication should be kept out of sight.

3.82 IF THE PATIENT IS OUT:

3.82.1 The driver leaves a failed delivery card and is asked to contact the pharmacy to re-arrange the delivery.

3.82.2 The driver returns to the pharmacy with any undelivered medication and the delivery record book. Undelivered medication must be handed to the RP.

3.83 DO NOT- Leave the delivery items.

3.83.1 Unattended in porches or on doorsteps

3.83.2 with children

3.83.3 neighbours - Unless arrangements have been made by the patient/carer and written consent is available

Choice of Packaging

3.84 The choice of packaging selected depends on the type and nature of the medication being packed.

3.85 The packaging must be selected in accordance to stability, security and maintaining integrity of the item. On all occasions tamper proof seals must be added to the final package before leaving the pharmacy. For non-fragile items within the local delivery range can be sent in standard pharmacy paper bags. All boxes used in the delivery process at any stage must be reinforced cardboard boxes.

3.86 For postal items all are packed in reinforced cardboard boxes surrounded in bubble wrap to ensure integrity of the items and should any fragile items be sent then in addition to this filling material is to be used to restrict movement of the item. Additionally, for glass bottles for instance, items are packed in air filled pouches to protect the package. For additional cold chain packaging please see the processes below.

National Delivery

3.87 Nationwide deliveries will be sent via recorded delivery via Royal Mail or an approved courier according to appropriateness, requiring a signature from the patient, their notified carer, or an authorised representative. Photographs are also taken of the handover of the packages. All medication is packaged appropriately within postal boxes or air protected envelopes and are labelled discreetly with no branding or mention of the contents, using bubble wrap or specific glass protection air containers. Patients will receive a tracking number to monitor their delivery status online and by text and will be informed about their delivery through a text messaging system. Medicines will be packed, transported, and delivered to preserve their integrity, quality, and effectiveness. The delivery process will provide a verifiable audit trail using a tracking code and access to the courier portal providing evidence of movement of parcel and signatures of receipts. If there is a return to the pharmacy in case of delivery failure this can also be tracked back using the same method. Postal delivery items will not be put through letter boxes or left unattended in porches on doorsteps, with children or with neighbours, unless arrangements have been made by patient/carer. This request would be obtained in writing from the patient/carer with a signature authorising delivery to another address. A signature is always required from the recipient to indicate safe receipt. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. On all other occasions, medication is packed into the pharmacy bag and placed into a reinforced postal box with bubble wrap. If necessary, polystyrene filler is used inside the postal box. The patient, carer, or authorised representative must always sign and date a receipt to confirm safe receipt of the medicines. The use of ‘Fragile’ stickers should be used. If the patient is not at home during the delivery attempt, they will be notified with a non-delivery notice, and an alternative delivery date will be arranged by the patient using their tracking code and delivery options or this can be done by the pharmacy if contacted. All confidentiality checks are done, including confirmation of name, address and postcode before any alterations are made to the delivery. All movements can be monitored at any time from within the pharmacy’s online portal and direct contact with the Royal Mail contact centre.

3.88 CD deliveries are carried out by Royal Mail who allow the patient more flexibility in monitoring and organising the exact time of delivery and to arrange and consent for any safe place or alternate delivery address requirements. Before sending CDs the patient is always notified by telephone that they are being despatched and to expect a tracking link. There is a daily online check to confirm the delivery signatures and statuses for controlled drugs. This is on a Tracked 24 service from Royal Mail.

Collection of Prescriptions

3.89 For the collection of prescriptions from doctor's surgeries, collected by the pharmacy’s own delivery driver - 2 address labels are generated. One is added to the branch record sheet, and collection is denoted by 'C'. The other is stuck to the delivery record book. The driver should sign the entry on the branch record sheet before leaving the pharmacy to ensure that they know a pickup is required.

3.90 On arrival at the surgery for collection, prescriptions are placed in a bag, and the receptionist signs the delivery record book. The bag is returned to the pharmacy.

Record Keeping

3.91 Delivery books and branch record sheets should be kept in the pharmacy for three months after completion.

Emergency Contingency Plans

3.92 If the driver is ill or unable to deliver as usual on any day, the Pharmacist should be contacted ASAP. Deliveries could be taken by pharmacy staff if possible, and if not, patients should be phoned to arrange delivery on a different day.

Cold Chain Deliveries

3.93 Local Pharmacy Driver

3.94 Fridge lines that are due for delivery can be dispensed in advance, packaged, labelled and stored in the dispensary refrigerator. Alternatively they can be dispensed immediately prior to leaving the premises. Dispensed medicines must remain refrigerated until immediately prior to leaving the premises. The process of the product leaving the pharmacy should be documented in the delivery log. On removal of any item from the base drug refrigerator, there will be a visual inspection of the product to ensure that it meets with the described physical appearance. Delivery routes should be planned so as to ensure fridge lines are delivered as soon as possible and the cold-chain is maintained. The recipient should be reminded to follow the manufacturer's instructions on domestic storage of the medicine. If a fridge line cannot be successfully delivered for any reason for local deliveries, then driver must return it to the pharmacy as soon as reasonably possible. The pharmacist must be satisfied that the cold chain has been maintained before deciding to issue the medication to the patient.

3.95 We use corrugated box liners in a cardboard box alongside cold packs to maintain the integrity of the cold chain for our deliveries by our drivers. The cardboard box liners are comprised of two identical pads for the top and bottom and four pads for each side. These products arrive flat-packed and are assembled by folding inwards and securing with the fitted seal and peel. This creates the high-quality insulating protection chilled packaging requires to deliver medication in the required cold-chain condition. Each corrugated pack fits exactly into two of our stock boxes for a secure fit unlikely to move about while being transported. When used together, every surface area of a box is thermally lined with a material designed to resist external changes in temperature from affecting the products inside. Temperatures will remain within 2-8 degrees for medication for up to 36 hours. This box is then further placed into a cooling bag with ice packs and an alarmed temperature data logger is put within the cooling bag. The data supporting the stability of the packaging we use is shown below. [see graph at Appendix A].

3.96 To audit any breach, after each delivery, the driver makes note of the temperature on the data logger in the driver logbook and the time of entry is also added. The driver is aware that should the temperature fluctuate outside of 2-8C then the entire cold chain delivery must be bought back to the pharmacy and the Responsible pharmacist notified. The patient must be contacted and arrangements for new stock to be delivered must be made. An investigation into the cause of the breach must be carried out immediately by the Responsible Pharmacist.

3.97 For local deliveries, even with a failed delivery the 36 hour stability time is ample time for the item to be returned to the pharmacy. In the event of an unsuccessful delivery, the driver will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or via their online portal with the pharmacy.

3.98 Calibrated temperature thermometers measuring minimum/maximum temperatures are used to ensure the integrity of the cold chain and the maximum stability of temperature-sensitive drugs by packing, transporting, and delivering them in a manner that preserves their integrity, quality, and effectiveness. We use an alarmed temperature and humidity data logger within the cooling bag to ensure temperatures remain between 2-8 degrees (as mentioned above). Once the driver is back at the pharmacy the USB data logger is placed into the pharmacy computer and a PDF is generated. Temperatures are then reviewed and should there have been an instance when the alarm was triggered or the temperature fell out of the desired range then that

would show. If this does happen it is referred to the Responsible Pharmacist and further steps taken accordingly.

Courier Service

3.99 When a non-local prescription is received for a cold chain prescription item, the pharmacy contacts the patient to arrange delivery. The pharmacy must ensure the following:

3.99.1 The patient will be available to sign for the delivery and an approved time slot by both pharmacy and patient is agreed

3.99.2 If the patient needs to change this time or method of receipt they must contact the pharmacy to arrange this by telephone

3.99.3 The patient is informed if the medication delivery fails they must contact the pharmacy by telephone to arrange re-delivery

3.99.4 The patient clarifies how they would like their delivery tracking number sent to them. This can be by telephone or email.

3.100 We dispense and package cold chain items in specialised pharmaceutical insulated thermal packaging maintaining a temperature between 2-8 degrees on the day they are due to be delivered. The item is put into the package with fleece liners and then put within thermal blockers. The thermal blockers protect the medication from direct contact with the ice packs which are also packed together. The item is then placed into the pharmacy fridge section labelled 'Courier Delivery' and a fridge label is attached. This remains in the fridge until it is ready to be transferred to the specialist cold chain courier.

3.101 Once the patient has agreed to accepting the delivery the details are entered onto the booking system of the courier to be used. These details include name, address and number of packages to be sent. If there are two cold chain items they are packed individually and count as 2 parcels for the same address. In this way each item within the package is identifiable. Later on in the process the tracking number is put alongside the name of the item in the pharmacy cold chain courier book.

3.102 When the approved cold-chain courier is selected, the final thermal package is placed into our reinforced postal box, labelled in discreet packaging and a tamper proof seal is put on the package.

3.103 Our process of packaging provides the medication within a range of 2-8 degrees for up to 54 hours. The data supporting our choice of packaging is shown below [see graph at Appendix A]. The range remains within the 2-8C for the duration of that time.

3.104 The package is then sent using an approved MHRA registered cold chain courier (a choice of which are available to use depending on the size of delivery and the availability to deliver in the required time to the patient). All cold chain couriers approved by the RP will provide strict and stringent processes to ensure the viability of the cold chain is maintained from collection to transport and then to final delivery to the patient. On collection of the packages the courier signs receipt from the pharmacy. Once handed over, the pharmacy cold chain courier book is completed with the tracking numbers being put alongside the patient name and the individual item names.

3.105 Each approved courier meets regulatory standards and offer a specialist service in transporting pharmaceuticals. The couriers use refrigerated vehicles and have refrigerated storage at each point throughout the delivery process. From dispatch to final-mile delivery the cold chain couriers have a fully monitored and transparent service. Should any breaches occur, the cold chain couriers will notify the pharmacy and the RP will be informed. The relevant steps outlined below will then be taken and

the patient contacted immediately by telephone to inform them of the breach and the steps which will take place to re-deliver new stock of the item.

3.106 At any stage of the delivery, the Responsible Pharmacist can ask for confirmation of the temperatures being maintained from the courier within the range and this can be audited throughout the delivery process. Post-delivery reports are also available to the pharmacy

3.107 Our processes have been designed to ensure end to end integrity of the cold chain and is designed to keep the patient informed throughout the process. We simplify and encourage communication to and from the patient with the pharmacy.

3.108 In the event of an unsuccessful delivery, the courier will leave a message for the patient, stating the date and time of the attempted delivery and a collection point or re-delivery options if this has been agreed with the patient in advance. The pharmacy can help rearrange delivery for a convenient time by telephone. All cold chain medication delivery confirmations are checked for delivery within 24 hours for signed receipt from the patient. If the package has not been signed for, the patient is contacted to confirm receipt and to support with any arrangements required.

Delivery Temperature Deviation Procedure

3.109 If it is found during delivery that the maximum/minimum thermometer readings are outside the ideal 8C and 2C and there is a concern that there has been a breach in the cold chain then this should be brought to the attention of the Responsible Pharmacist. In this event, please follow these procedures.

Temperature deviation due to malfunction

3.110 If the temperature has deviated during a malfunction, move the medication to an alternate fridge and give a list of the affected boxes, and the temperature at the time of the move then document this discrepancy in the pharmacy error log.

Temperature deviation due to power outage

3.111 If a power outage occurs alternative arrangements for cold storage must be deployed. This includes, but is not limited to, using the back-up fridge. This error will need to be logged in the pharmacy error log.

Processing of temperature damaged items

3.112 Immediate action upon identification of damaged items

3.113 Should the minimum recording of the temperature be less than 0C then the stock in the refrigerator should be quarantined by placing it into an appropriate container or bag and labelling the container or bag ‘DO NOT USE’. The stock will be then disposed of according to the Standard Operating Procedure on the disposal of unwanted medicines.

Identification of temperature deviation post-delivery

3.114 If the breach of the cold chain is discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review.

3.115 In all instances, whether for local or national delivery or whether a cold chain or non-cold chain the pharmacy will always provide delivery estimates for delivery. This is done by the pharmacy updating the online portal as well as sending a text message to the patient. This information is always available if a patient calls the pharmacy. Should

there be any delay in delivery then times are updated accordingly. Please see screenshots below [see Appendix A].

Supply in accordance with a Pandemic Treatment Protocol (PTP)

3.116 The following conditions must apply to the request:

3.116.1 The message is received via a secure service approved by NHSCB

3.116.2 The message must amount to an order for the supply of the drug

3.116.3 The order must be in accordance with a PTP

3.117 All PTP orders must be referred to the RP who should review the relevant PTP and ensure compliance with its terms. Should a person be entitled for supply then the pharmacy should promptly provide that drug using the relevant delivery methods described above.

Listed Prescription Item Voucher schemes (LPIV)

3.118 As per PSNC Briefing 050/21 - A Listed Prescription Item Voucher (LPIV) scheme is introduced, a further option for the community pharmacy supply of treatments or medicines during or in anticipation of pandemic disease. This may be used for the supply of medicines without charge to the patient.

3.119 The LPIV is slightly wider in scope (e.g. any medicines not only POMs; and any emergency that threatens or has caused serious damage or risk to public health in any part of England rather than limited to a pandemic). With the LPIV:

3.119.1 NHSE&I provide an electronic voucher through a secure system to a community pharmacy. If the item is a POM, the voucher will be a prescription from an authorised prescriber but will not be an ordinary FP10 prescription.

3.119.2 Following receipt of the voucher, the community pharmacy, must supply the medicine with reasonable promptness to a person entitled to receive the medicine.

3.120 Aspects of the Essential service dispensing service apply including giving a time estimate of when the item will be ready, and supply may be refused if for example, the pharmacist does not consider this is an LPIV for the person requesting the medicine or the person's representative, or supply would be contrary to the pharmacist's clinical judgement.

3.121 Records must be kept and are updated on the pharmacy PMR notes under the patients details.

Refusal to Supply a Medication, including under a PTP and LPIV

3.122 The pharmacy may refuse supply of a medication order when:

3.122.1 The RP believes it is not a genuine order

3.122.2 It is contrary to the RP's clinical judgement

3.122.3 The RP or member of the pharmacy team is threatened with violence by the person requesting medication

3.122.4 The person requesting the medication commits or threatens to commit a criminal offence

3.123 All refusals must be noted in the PMR / pharmacy record and the reason for refusal clearly noted.

Protocol for Handling EPS Service Downtime

3.124 The pharmacy will ensure continuity of care and provide alternative options for patients when the Electronic Prescription Service (EPS) is temporarily unavailable.

Procedure:

3.125 Identification of EPS Downtime:

3.125.1 Monitor the EPS system regularly to identify any downtime or service disruptions.

3.125.2 Confirm the downtime by checking with the EPS support team or relevant authority.

3.126 Immediate Actions:

3.126.1 Notify all relevant staff members about the EPS downtime.

3.126.2 Update the pharmacy's website and automated phone message to inform patients about the temporary unavailability of the EPS service.

3.127 Alternative Pharmacy Contact Information:

3.127.1 Provide patients with contact details for at least two local pharmacies where EPS is available. This will need to be ascertained from the patient's location and the choice of if they would like to visit a face-toface pharmacy or have the alternate service provided by a Distance Selling Pharmacy.

3.128 Communication with Patients:

3.128.1 Inform patients contacting the pharmacy about the EPS downtime and provide them with the contact details of the alternative pharmacies.

3.128.2 Offer assistance in contacting the alternative pharmacies if necessary.

3.129 Providing Updates:

3.129.1 Keep patients informed about the status of the EPS service through regular updates on the pharmacy's website, social media channels, and automated phone messages.

3.129.2 Notify patients once the EPS service is restored.

3.130 Support and Assistance:

3.130.1 Provide additional support to patients who may have difficulty accessing alternative pharmacies.

3.130.2 Ensure all staff members are trained to handle patient queries and provide appropriate guidance during the EPS downtime.

3.131 Documentation:

3.131.1 Record all incidents of EPS downtime, including the duration and actions taken.

3.131.2 Maintain a log of patient communications and any assistance provided.

3.132 Review and Evaluation:

3.132.1 Conduct a review after each EPS downtime incident to evaluate the effectiveness of the protocol.

3.132.2 Identify any areas for improvement and update the protocol as necessary.

3.133 By following this protocol, our pharmacy ensures that patients have continuous access to their medications and receive the necessary support during any EPS service disruptions.

Providing Advice To Patients Remotely

3.134 The RP will counsel patients receiving medication and appliances remotely. The RP will make arrangements to speak to the patient by telephone or videocall to ensure patients are advised correctly and promptly. The pharmacy will follow the below protocols for this.

Patient Advice on Medication Use

3.135 Dosage and Administration

3.135.1 Advise patients to follow the prescribed dosage and administration instructions.

3.135.2 Recommend the use of medication reminder tools (apps, pill organisers).

3.136 Storage Instructions

3.136.1 Inform patients about the correct storage conditions (e.g., cool, fridge, away from direct sunlight).

3.136.2 Emphasise the importance of keeping medications out of reach of children and pets.

3.137 Side Effects and Interactions

3.137.1 Explain common side effects and what to do if they occur.

3.137.2 Ask patients to inform the pharmacy of any other medications or supplements they are taking.

Patient Advice on Appliance Use

3.138 Assembly and Setup

3.138.1 Provide clear instructions for assembling and setting up appliances.

3.138.2 Offer remote assistance via videocall if patients encounter difficulties during setup.

3.139 Proper Use

3.139.1 Educate patients on the correct use of the appliance as per healthcare provider's instructions.

3.139.2 Stress the importance of maintaining a clean and hygienic environment.

3.140 Maintenance and Storage

3.140.1 Advise on regular cleaning and maintenance as per the manufacturer's guidelines.

3.140.2 Suggest appropriate storage solutions to ensure the appliance's longevity.

Providing Additional Support

3.141 Consultations

3.141.1 Offer remote consultations with pharmacists for personalised advice via telephone and videocall.

3.141.2 Ensure secure messaging services are available for patient enquiries.

3.142 Emergency Protocols

3.142.1 Provide patients with an emergency contact number for urgent medication-related queries.

3.142.2 Remind patients to contact emergency services in case of medical emergencies.

Disposal of Medications/Appliances

3.143 Disposal Instructions

3.143.1 Inform patients about local disposal guidelines for unused or expired medications as well as the availability for the pharmacy to collect unwanted medication from the patients home.

3.143.2 Guide patients on the proper disposal of appliances as per manufacturer's instructions.

3.143.3 Advise medication should not be disposed of in general waste and advise on the types of medication and types of disposal required.

Follow-Up and Feedback

3.144 Follow-Up Calls

3.144.1 Schedule follow-up calls to check on patient compliance and address any concerns.

3.144.2 Document any issues raised by patients for continuous improvement and make a note in the PMR.

3.145 Feedback Collection

3.145.1 Encourage patients to provide feedback on the service.

3.145.2 Use feedback to enhance patient care and service delivery.

Record Keeping and Documentation

3.146 Record Maintenance

3.146.1 Maintain accurate records of all patient interactions and advice provided on the patient portal and on the pharmacy PMR

3.146.2 Ensure all documentation complies with regulatory requirements and data protection laws.

Staff Training and Development

3.147 Continuous Training

3.147.1 Provide regular training sessions for staff on patient communication and remote support.

3.147.2 Update staff on any new medications, appliances, and protocols.

3.148 Quality Assurance

3.148.1 Implement quality assurance measures to ensure consistent and high-quality patient advice.

3.148.2 Regularly review and update procedures to align with best practices and regulatory changes.

Repeat Dispensing

3.149 Assessing a patient as to their need for a repeat prescription remotely.

3.150 Repeat prescriptions will be dispensed as per our Dispensing of Prescriptions and Repeat Dispensing SOPs as per below with the addition of offering the service to patients for storing the documentation if required. An appropriate pharmacy record card will 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 will be recorded in the comment section of the pharmacy copy of the card.

3.151 Supply will only be made when medication is required and when no changes have occurred that would require referral back to the GP. Before any issuance of a repeated prescription, all patients are asked the following questions via the telephone or video consultation.

3.151.1 Did you experience any side effects from your last prescription?

3.151.2 Are you experiencing any issues with your last prescription?

3.151.3 Did your last prescription arrive at your delivery address damaged?

3.151.4 Have there been any changes to your health since the issuance of this prescription which would lead to you not requiring it?

3.152 Responding to a patient indicated need.

3.153 The Responsible Pharmacist will telephone/video call the patient before issuing a repeat and ensure:

3.153.1 They are taking or using, and likely to continue to take or use the medicine or appliances appropriately.

3.153.2 Advise the patient that they should only order items that they need.

3.154 Check that the patient is not suffering any side effects which may suggest they need a review of their medication.

3.154.1 Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

3.154.2 Check that there has not been any change to the patient's health since the prescription was authorised.

3.154.3 Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

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

3.156 Identify a repeat dispensing co-ordinator for your pharmacy.

3.156.1 Whilst not a requirement for the implementation of repeat dispensing, the pathfinder sites have reported the benefits of identifying someone within your pharmacy, not necessarily the pharmacist, to co-ordinate the service.

3.157 Promote Repeat dispensing.

3.157.1 Promote eRD and identify suitable patients for the GP practice(s) as per Essential Service in Pharmacy Contract, by using the 'suitable for eRD' stamp. Contact the patient by phone.

3.158 Identify suitable patients.

3.158.1 Repeat dispensing will only suitable at this stage for people with stable long-term conditions and on 4 or less regular medicines who are likely to remain on the same medication for the duration of the batch issue

3.158.2 NHSBSA data will be provided to highlight patients suitable for the switch to eRD by NHS number for individual practices. Schedule 2 and 3 Controlled Drugs cannot be prescribed on eRD. Schedule 4 and 5 Controlled drugs can be prescribed, however, there are conditions for dispensing (GP/Senior PCN Pharmacist to authorise on a per-patient basis)

3.158.3 Unlicensed specials are not suitable for eRD

3.158.4 Medications requiring frequent review such as acute medicines, warfarin, methotrexate, lithium, DMARDs and benzodiazepines and hypnotics are not suitable for eRD Obtain consent remotely by phone or video.

3.158.5 Ensure there is a robust system for passing on messages from the practice to the pharmacist about monitoring requirements to avoid problems when the next repeat is requested.

3.158.6 Patients signing up to this service must consent to the sharing of the information between the pharmacy and GP surgery. Ensure that consent for the eRD and EPS has been appropriately recorded. This can be by telephone, email, videocall, post or by a message on the patient online platform. If patient changes their nominated pharmacy at any time their eRD prescriptions (including any remaining batches) will be issued to the newly nominated pharmacy.

3.159 Check items are needed.

3.160 Check and confirm with the patient by telephone or the agreed contact method what items the patient requires at each dispensing. Record any items not dispensed. All electronic messages from the GP must be sent to the patient via the online portal or they are printed and posted to the patient.

Receiving Prescriptions

3.161 The eRD will be automatically sent to the pharmacy or the patient may send the token by freepost.

3.162 The token can be used to retrieve the prescription from the NHS spine as per the PMR system's process. Check the repeatable prescription is not more than 6 months old or 28 days for Schedule 4 Controlled Drugs. Subsequent batch issues are valid for 12 months from the signed date. Print off the prescription, label and assemble the items following the appropriate SOP.

3.163 Final issue of a repeat.

3.164 Contact the patient by phone and inform patient when the final issue has been dispensed and advise them to contact the practice. Ensure all documents are used correctly stored as this will be helpful for audit purposes. A Claim Notification should be submitted to the NHS Spine as per PMR process.

Disposal of Unwanted Medication

3.165 For patients within the local driver radius who contact the pharmacy by telephone or the agreed contact method to arrange a collection as there is no face-to-face interaction with the pharmacy.

3.166 Drivers collect the returned medication and store appropriately in the identified area in the pharmacy when returning and organised accordingly.

3.167 For requests for CD returns, the Responsible Pharmacist must be notified and arrange to speak directly to the patient. The name, strength and quantity to be returned must be ascertained and then the collection organised. On return to the pharmacy the driver must hand the controlled drug directly to the responsible Pharmacist who will then follow the GPhC guidelines on the destruction of controlled drugs. Controlled drug returns should not be mixed in the same area as stock and the separate CD cupboard allocated for returned CDs only. Destruction must be witnessed by an appropriate officer for the local area. The correct entry must then be made in the CD destruction book.

3.168 When collecting a returned medication from a patient not within a local collection area, a tracked Royal Mail collection is organised with the patient. The same procedure as mentioned above with regards to CDs should be followed.

3.169 The pharmacy cannot accept waste from nursing homes. The pharmacy cannot accept sharps or clinical waste. Local procedures should be advised as well as signposting to the most appropriate service. Returns from patients homes are collected via an approved NHS contractor, currently PHS. A collection note must be received on completion of the collection.

Signposting

3.170 Minimising inappropriate use of health and social care services

3.171 Our pharmacy considers it the duty of any Responsible Pharmacist working for us to minimise inappropriate use of health and social care services and of support services as a day-to-day activity. All patients that cannot be provided with adequate help and support will be referred or signposted to other health and social care providers or

support organisations who may be able to assist the person accordingly. Information can be provided by telephone, online or by posting available literature to the patient. Staff ask WWHAM questions by telephone or video consultation and when needed refer to the Responsible Pharmacist for further history taking.

3.172 Recording the referral

3.173 The pharmacist will make a note of the referral if deemed necessary and will provide a written referral note if required. Signposting will be carried out equally when approached either by email or on the phone. Where advice cannot be provided this should be recorded as an Intervention on the patient record along with the referral organisation. The pharmacy has a list of local services available and if the patient is not a local, then the pharmacy can assist them by pointing out those services closest to them through the NHS Choices website or the NHS 111 service if necessary. Focal Point also has links to main health topics to the NHS Choices website through the website.

Promotion of Healthy Lifestyles and Health Campaigns

3.174 Prescription receipt

3.175 If a non-electronic prescription or non-electronic repeatable prescription is presented to the pharmacy by post, the patient will be contacted via telephone or the preferred contact method. Upon consultation, if the pharmacist notices on clinical review that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face-to-face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through leaflets to be delivered to patients' home. Where advice is provided it should be recorded on the PMR. The email newsletter and website will also be used to promote a healthy lifestyle. Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

3.176 Health Campaigns

3.177 The Pharmacy will actively engage in national health campaigns to disseminate health messages to our patients throughout England. This will involve distributing leaflets along with prescriptions during targeted campaign periods and offering additional advice and educational materials through when requested by telephone or email. Patients will also receive information via emails regarding health campaigns throughout the year.

3.178 Patients will receive guidance on accessing these learning resources via email, text messages, and other forms of non-face-to-face communication to ensure awareness of the campaigns.

3.179 Additionally, patients will be evaluated for participation in at least one clinical audit and any other audits specified by the NHSCB. These audits may include clinical audits conducted in accordance with NHSCB data processing arrangements or policy-based audits designed to support the development of NHSCB commissioning policies, all of which will comply with NHSCB data processing protocols.

3.180 These campaigns are recorded and the patients involved have a note added to their PMR with the specific details.

3.181 All information relating to NHS Essential Services will appear on the website which will be regularly updated to reflect current campaigns. The pharmacy is able to contact patients via email to confer public health campaigns.

Discharge Medicines Service

3.182 Preparation for the service.

3.183 Pharmacists and Pharmacy Technicians (including locums) providing the service must:

3.183.1 Ensure capability and availability to carry the service out in a none face-to-face method

3.183.2 Read the DMS sections within NHSE&I guidance on regulations

3.183.3 Read the NHSE&I DMS Toolkit

3.183.4 Complete the CPPE 'NHS DMS - Declaration of Competence' (DoC)

3.183.5 Provide copy of completed DoC to pharmacy contractor

3.184 All staff involved in providing the service must:

3.184.1 Have received appropriate training necessary to support their role within the service

3.184.2 Be briefed on the DMS and received adequate training on the service operation

3.184.3 Read and understand the contents of this SOP

3.184.4 Understand the referrals process and requirements for checking IT systems.

3.184.5 https://cpe.org.uk/wp-content/uploads/2021/02/Discharge-Medicines-Service-activitysummary.pdf

3.185 Patient Referrals

3.185.1 Check appropriate IT systems for patient referrals - Agree suitable timings within day

3.185.2 Confirm minimum requirements of information have been provided on the referral (Appendix 2) and start the DMS Stage 1

3.185.3 If information is missing contact details of referring clinician/hospital department.

3.186 DMS - Stage 1 (Completed as soon as possible, but within 72hrs* on receipt of referral) (*excludes hours of days when pharmacy not open)

3.186.1 Check referral for clinical information and actions required

3.186.2 Check all previously ordered prescriptions for the patient (including any awaiting delivery is still appropriate.

3.187 Pay particular attention to electronic repeat dispensing prescriptions as may be pulled down from the NHS spine a while after patient has been discharged.

3.187.1 Compare post discharge list of medicines with those being taken before admission.

3.187.2 If necessary, raise any issues identified with the NHS Trust or Patient's GP, as appropriate.

3.187.3 Record notes as appropriate on the PMR system and/or other appropriate record.

3.187.4 Ensure flag in place on record to alert staff of the need to complete Stages 2 and 3, when o first prescription received, or

3.187.4.1first contact with patient/carer

3.188 DMS - Stage 2 (Completed when 1st Prescription received following discharge, Usually with 1 week to 1 month following discharge)

3.188.1 Check medicines prescribed reflect appropriate changes made during the hospital discharge

3.188.2 Any discrepancies / issues to be raised with GP practice to try and resolve

3.188.3 Record notes as appropriate on the PMR system and/or other appropriate record.

3.189 DMS - Stage 3 (Remote confidential discussion with patient/carer on dispensing of this 1st prescription)

3.189.1 Conduct a confidential conversation with the patient / carer to check their understanding of the medicines. This is done via telephone / video call.

3.189.2 Adopting a 'shared decision making' approach to improve compliance / adherence

3.189.3 If any information discussed, is considered to be clinically appropriate to support patients' on going care, it should ideally be shared with patient's general practice/PCN pharmacy team

3.189.3.1 Gain patient consent to share, and record on notes.

3.189.3.2 Send notes using a secure method

3.189.4 If appropriate, offer to dispose of medicines no longer required by non face to face contact, to avoid any potential confusion.

3.189.5 Record notes as appropriate on the PMR system and/or other appropriate record.

3.190 All stages of DMR cannot be completed

3.190.1 If the above normal patient journey through the service cannot be complete

3.190.2 Pharmacist/pharmacy technician to use professional judgement to determine the appropriate actions to take. (see appendix 3 for details of examples).

Support for Self-Care

3.191 Defining Self Care

3.192 There are a wide range of self-care support interventions. These have varying levels of intensity, differences in content, and a range of theoretical underpinnings (from didactic education to the use of behavioural counselling techniques and theories of behaviour change). The goal is to empower individuals with greater understanding of their treatment options and to reduce unnecessary utilisation of health and social care services.

3.193 The advice provided encompasses:

3.193.1 Provision of advice to people, including carers, requesting helping with the treatment of minor illness and long-term conditions, including general information and advice on how to manage illness

3.193.2 Provision of advice on appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions

3.193.3 Provision of healthy lifestyle interventions when appropriate for promotion of healthy lifestyle service

3.193.4 Signpost patients to other health and social care providers when appropriate

3.194 Providing Self Care

3.195 We will endeavour to provide maximum support from the pharmacy to enable people to care for themselves or their families. There are a range of topics ranging from long-term conditions to minor ailments via our website which links to the NHS Choices website for up-to-date information and support and also if the patient would like more in-depth scientific knowledge about medication or health conditions. Self-care our pharmacy intends to provide to our patients include:

3.195.1 information-giving

3.195.2 addressing motivations and barriers to change

3.195.3 teaching coping strategies

3.195.4 designing action plans

3.195.5 dealing with emotional illness

3.195.6 ongoing monitoring/support

3.195.7 engaging family and social support

3.196 Opportunistic self-care

3.197 The support for self-care will also be provided opportunistically if a patient or carer telephones the pharmacy for advice or books a video consultation. A note will be made of any advice given to patients whether online or over the phone if deemed necessary. This service intertwines of course with signposting and public health promotion. A record should be made in the PMR."

4 Summary of Representations

No representations were received by NHS Resolution in response to the appeal.

5 Consideration

5.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution had before it the papers considered by the Commissioner.

5.2 It also had before it the responses to NHS Resolution's own statutory consultations.

5.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

5.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

5.5 The Committee first considered Regulation 31 of the Regulations which states:

(1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

5.6 The Committee noted that the Applicant had simply stated "n/a" in the relevant section in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

5.7 Further the Commissioner has not considered Regulation 31 in its decision.

5.8 Given no party has sought to argue that Regulation 31 would require the Committee to refuse the application, the Committee determined that it was not required to refuse the application under this provision.

5.9 The Committee had regard to Regulation 24(1) which requires the following five conditions to be met:

(a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;

(b) in the opinion of NHS England, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—

(i) in any part of the area of HWB1, or

(ii) in a controlled locality of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;

(c) NHS England is not of the opinion that granting the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB1;

(d) the services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises (whether or not, in the case of enhanced services, NHS England chooses to commission them); and

(e) the provision of pharmaceutical services will not be interrupted (except for such period as NHS England may for good cause allow).

Regulation 24(1)(a)

5.10 In relation to 'distance-selling' of essential services, the Committee considered that no issue arose as no such services are being accessed at the existing premises. Further the Committee noted the Applicant does not intend on providing any advanced or enhanced services at the proposed site.

5.11 The Committee was therefore of the view that condition (a) is met.

Regulation 24(1)(b)

5.12 The Committee noted the Commissioner had not considered Regulation 24(1)(b) in its decision. Further no party had sought to argue that the application should be refused pursuant to this provision.

5.13 Therefore on the information available the Committee was of the opinion that the granting of the application would not result in a significant change to the arrangements in place for the provision of local pharmaceutical services or of pharmaceutical services in any part of the area of HWB1 or in a controlled locality of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate. The Committee concluded that condition (b) is met.

Regulation 24(1)(c)

5.14 The Committee noted the Commissioner had not considered Regulation 24(1)(c) in its decision. Further no party had sought to argue that the application should be refused pursuant to this provision.

5.15 On the information provided the Committee was of the opinion that the granting of the application would not cause a significant detriment to the proper planning in respect of the provision of pharmaceutical services in the area of HWB1 and therefore concluded that condition (c) is met.

Regulation 24(1)(d)

5.16 The Committee noted that the Applicant had given an undertaking, in its application form, that the same services will be provided at the proposed site. On the information provided, the Committee determined that condition (d) is met.

Regulation 24(1)(e)

5.17 In relation to condition (e), the Committee noted the Applicant had confirmed in its application form that there will be no interruption to service provision. On the information provided the Committee determined that condition (e) is met.

Regulation 24(3)(d)

5.18 The Committee noted that the application is for the relocation of a distance selling pharmacy.

5.19 The Committee therefore needed to have regard to Regulation 24(3)(d) which states:

> *(3) An application pursuant to this regulation must be refused if the existing pharmacy premises from which the applicant is seeking to relocate (P3) –*
>
> *(d) are distance selling premises, unless –*
>
> *(i) the premises to which the applicant is seeking to relocate are also distance selling premises, and*
>
> *(ii) if the application was one to which regulation 25(2) applied, it would not be refused pursuant to regulation 25(2).*

5.20 In relation to Regulation 24(3)(d)(i), the Committee noted that Applicant at paragraph 9.1 of the application form has ticked the box "Yes" in answer to the question "Are you applying for a relocation to distance selling premises?". The Committee was satisfied that the Applicant's current premises and the premises to which the Applicant is seeking to relocate are both distance selling premises.

5.21 In relation to Regulation 23(d)(ii), the Committee had regard to Regulation 25, which states:

> *(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—*
>
> *(a) for inclusion in a pharmaceutical list by a person not already included; or*
>
> *(b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person, in respect of pharmacy premises that are distance selling premises.*
>
> *(2) NHS England must refuse an application to which paragraph (1) applies—*
>
> *(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and 13*
>
> *(b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*
>
> *(i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
>
> *(ii) 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 applicant or the applicant's staff.*

5.22 The Committee also had regard to the provisions of Schedule 2 to the Regulations shown below:

> *8. If the applicant (A) is making an excepted application, A must include in that application details that explain—*
>
> *(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and*
>
> *(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.*
>
> *Nature of details to be supplied*
>
> *10. Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

5.23 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list as a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person, and paragraph (1)(b) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

5.24 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

5.25 Further the Commissioner had not considered Regulation 25(2)(a) in its decision.

5.26 Given no party had sought to argue that Regulation 25(2)(a) would require the Committee to refuse the application, and based on the information available to it, the Committee determined that the proposed premises were not on the same site as, or in the same building as, the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

5.27 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services.

5.28 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.

5.29 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.

5.30 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the Applicant's appeal.

5.31 The Committee has sought evidence within the application and appeal in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

5.32 With regard to services being provided without interruption, the Committee noted the Applicant states that there will be an "*RP on site at all times*". Further the Applicant states:

5.32.1 *"Care Quality Pharmacy provides uninterrupted service provision for the duration of the pharmacy's opening hours and has a full time Responsible Pharmacist in charge of all pharmacy operations and clinical decisions".*

5.33 However the Committee was of the view that it is not clear from the information provided, how essential services would be provided, should they be required, during the absence of the Responsible Pharmacist. This suggested to the Committee that there may be periods of interruption.

5.34 Therefore the Committee could not be satisfied, as it is required to be, that the provision of services would be without interruption.

5.35 The Committee considered how the Applicant would provide essential services without face to face contact and noted the Applicant states:

5.35.1 *"The pharmacy will use telephone, email, video-conferencing, or other types of non-face-to-face communications including text messages to contact patients."*

5.36 The Committee was aware that following the change of ownership, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

5.37 With regard to services being available to persons anywhere in England, the Committee noted the Applicant states:

5.37.1 *"NHS Essential Services will be provided to any patient living in England who requires such services, as stated on our website and in our practice leaflets."*

5.38 The Committee was satisfied that the provision of services would be without face to face contact and would be available to persons anywhere in England.

5.39 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

5.40 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

5.41 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:

5.41.1 Dispensing of drugs and appliances

5.41.2 Urgent supply without a prescription

5.41.3 Preliminary matters before providing ordered drugs or appliances

5.41.4 Providing ordered drugs or appliances

5.41.5 Refusal to provide drugs or appliances ordered

5.41.6 Further activities to be carried out in connection with the provision of dispensing services

5.41.7 Disposal service in respect of unwanted drugs

5.41.8 Promotion of healthy lifestyles

5.41.9 Prescription linked intervention

5.41.10 Health campaigns

5.41.11 Signposting

5.41.12 Support for self-care

5.41.13 Discharge medicines service

5.41.14 Websites and health promotion zones

5.42 The Committee was of the opinion that the procedures adopted by the pharmacy were likely to secure the safe and effective provision by the Applicant of the following essential services:

Dispensing of drugs and appliances

5.43 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

5.44 In its representations, at paragraph 3.17 above, the Applicant states:

5.44.1 *"Patients can also contact the pharmacy by telephone and consent to the pharmacy to nominate the patient. Prescriptions can also be sent to the pharmacy via post and the pharmacy has a pre-paid Royal Mail account.*

When prescriptions come in by post or from collection by the delivery driver they are checked for legal and clinical appropriateness by the Responsible Pharmacist and then dispensed accurately following SOPs".

5.45 Paragraph 3.37 states:

5.45.1 *"An emailed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received."*

5.46 Paragraph 3.69 states:

5.46.1 *"Pharmacy deliveries are carried out either using a pharmacy driver, Royal Mail or an approved courier partner. Factors such as type of medication and location are considered when selecting the delivery method. For local deliveries we operate within a 30 mile radius."*

5.47 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

5.48 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.

5.49 Paragraph 3.29 states:

5.49.1 *"When a prescriber (doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, optometrist or pharmacist nurse prescriber) makes a request for medication without a valid prescription by phone, then the pharmacist should speak to the prescriber. A faxed prescription should be authenticated by phone. The prescriber must provide the pharmacy with a valid prescription within 72 hours for the telephoned prescriptions. The pharmacy must supply the prescription-only medication according to the directions and quantity requested by the prescriber."*

5.50 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

5.51 The Committee considered whether the Applicant had explained how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.

5.52 Paragraphs 3.19 – 3.25 above state:

5.53 *"Receiving Hardcopy FP10 NHS prescriptions*

NHS prescription may arrive at the pharmacy in either an electronic form (via ETP) or in hardcopy form via an FP10 (green prescription) through post or delivery driver. In regards to hardcopy, the patient or their representative must complete the relevant sections of the reverse of the FP10DT EPS dispensing token to claim exemption from NHS prescription charge payment & the Pharmacist should check this is completed with the patient / their representative by telephone or by the agreed contact method.

Electronic checking.

In accordance with regulation 3(1) or (1A) of the Charges Regulations(1), before providing any drugs or fulfilling a prescription form or a repeatable prescription, our Responsible Pharmacist will determine whether any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified.

If the patient declares a specific exemption, they will be eligible to receive free NHS prescriptions from our pharmacy. This is checked through Real Time Exemption Checking (RTEC) functionality.

Invalid Exemptions

In the event, that the patient declares an exemption and the RTEC shows this to be invalid, patients may submit hardcopy proof of exemption to the pharmacy for validation. Document(s) can be sent to the pharmacy for verification via the delivery driver and then later returned to the patient. The PMR system would then 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 (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan or email a copy of the evidence to the pharmacy (or use the postal / courier service). This is done by sending it using a pre-paid envelope that can be obtained by post from the pharmacy. The pharmacy can record that the evidence provided was not in the original format. It is the pharmacist in charge who determines if the evidence is satisfactory; if not, they should check the 'Evidence not Seen' box. Exemptions sent to the pharmacy by post will have postage paid by the pharmacy, and the exemption will be returned to the patient free of charge.

The type of exemption and its expiry date will be recorded in the Patient Medication Record (PMR)."

5.54 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

5.55 The Committee considered whether the Applicant had explained how charges will be paid.

5.56 Paragraphs 3.26 and 3.27 state:

5.56.1 *"If the patient is not exempt, prescription charges will be processed through a secure online payment method.*

The pharmacy provides a number of options for patients to pay for their prescriptions, including 'pay-by-link', BACS transfer or by phone. For local deliveries payment is taken by card or cash if appropriate, by the driver."

5.57 On the basis of the information above, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

5.58 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

5.59 In relation to deliveries of controlled drugs, paragraph 3.69 states:

5.59.1 *"Pharmacy deliveries are carried out either using a pharmacy driver, Royal Mail or an approved courier partner. Factors such as type of medication and location are considered when selecting the delivery method. For local deliveries we operate within a 30 mile radius."*

5.60 Paragraph 3.79 states:

5.60.1 *"If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry. CD's are always packaged separately from other medication and a CD sticker attached to the bag. The items are placed in a coded locked safe box within the vehicle to keep them secure. Additionally, all vehicles are locked each time the driver leaves. The type of vehicle used is always a van with no rear windows, minimising any potential break in risk."*

5.61 Paragraph 3.88 states:

5.61.1 *"CD deliveries are carried out by Royal Mail who allow the patient more flexibility in monitoring and organising the exact time of delivery and to arrange and consent for any safe place or alternate delivery address requirements. Before sending CDs the patient is always notified by telephone that they are being despatched and to expect a tracking link. There is a daily online check to confirm the delivery signatures and statuses for controlled drugs. This is on a Tracked 24 service from Royal Mail."*

5.62 In relation to cold chain deliveries, paragraphs 3.93 – 3.109 state:

5.63 *"Local Pharmacy Driver*

Fridge lines that are due for delivery can be dispensed in advance, packaged, labelled and stored in the dispensary refrigerator. Alternatively they can be dispensed immediately prior to leaving the premises. Dispensed medicines must remain refrigerated until immediately prior to leaving the premises. The process of the product leaving the pharmacy should be documented in the delivery log. On removal of any item from the base drug refrigerator, there will be a visual inspection of the product to ensure that it meets with the described physical appearance. Delivery routes should be planned so as to ensure fridge lines are delivered as soon as possible and the cold-chain is maintained. The recipient should be reminded to follow the manufacturer's instructions on domestic storage of the medicine. If a fridge line cannot be successfully delivered for any reason for local deliveries, then driver must return it to the pharmacy as soon as reasonably possible. The pharmacist must be satisfied that the cold chain has been maintained before deciding to issue the medication to the patient.

We use corrugated box liners in a cardboard box alongside cold packs to maintain the integrity of the cold chain for our deliveries by our drivers. The cardboard box liners are comprised of two identical pads for the top and bottom and four pads for each side. These products arrive flat-packed and are assembled by folding inwards and securing with the fitted seal and peel. This creates the high-quality insulating protection chilled packaging requires to deliver medication in the required cold-chain condition. Each corrugated pack fits exactly into two of our stock boxes for a secure fit unlikely to move about while being transported. When used together, every surface area of a box is thermally lined with a material designed to resist external changes in temperature from affecting the products inside. Temperatures will remain within 2-8 degrees for medication for up to 36 hours. This box is then further placed into a cooling bag with ice packs and an alarmed temperature data logger is put within the cooling bag. The data supporting the stability of the packaging we use is shown below. [see graph at Appendix A].

To audit any breach, after each delivery, the driver makes note of the temperature on the data logger in the driver logbook and the time of entry is also added. The driver is aware that should the temperature fluctuate outside

of 2-8C then the entire cold chain delivery must be bought back to the pharmacy and the Responsible pharmacist notified. The patient must be contacted and arrangements for new stock to be delivered must be made. An investigation into the cause of the breach must be carried out immediately by the Responsible Pharmacist.

For local deliveries, even with a failed delivery the 36 hour stability time is ample time for the item to be returned to the pharmacy. In the event of an unsuccessful delivery, the driver will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or via their online portal with the pharmacy.

Calibrated temperature thermometers measuring minimum/maximum temperatures are used to ensure the integrity of the cold chain and the maximum stability of temperature-sensitive drugs by packing, transporting, and delivering them in a manner that preserves their integrity, quality, and effectiveness. We use an alarmed temperature and humidity data logger within the cooling bag to ensure temperatures remain between 2-8 degrees (as mentioned above). Once the driver is back at the pharmacy the USB data logger is placed into the pharmacy computer and a PDF is generated. Temperatures are then reviewed and should there have been an instance when the alarm was triggered or the temperature fell out of the desired range then that would show. If this does happen it is referred to the Responsible Pharmacist and further steps taken accordingly.

Courier Service

When a non-local prescription is received for a cold chain prescription item, the pharmacy contacts the patient to arrange delivery. The pharmacy must ensure the following:

- *The patient will be available to sign for the delivery and an approved time slot by both pharmacy and patient is agreed*
- *If the patient needs to change this time or method of receipt they must contact the pharmacy to arrange this by telephone*
- *The patient is informed if the medication delivery fails they must contact the pharmacy by telephone to arrange re-delivery*
- *The patient clarifies how they would like their delivery tracking number sent to them. This can be by telephone or email.*

We dispense and package cold chain items in specialised pharmaceutical insulated thermal packaging maintaining a temperature between 2-8 degrees on the day they are due to be delivered. The item is put into the package with fleece liners and then put within thermal blockers. The thermal blockers protect the medication from direct contact with the ice packs which are also packed together. The item is then placed into the pharmacy fridge section labelled 'Courier Delivery' and a fridge label is attached. This remains in the fridge until it is ready to be transferred to the specialist cold chain courier.

Once the patient has agreed to accepting the delivery the details are entered onto the booking system of the courier to be used. These details include name, address and number of packages to be sent. If there are two cold chain items they are packed individually and count as 2 parcels for the same address. In this way each item within the package is identifiable. Later on in the process the tracking number is put alongside the name of the item in the pharmacy cold chain courier book.

When the approved cold-chain courier is selected, the final thermal package is placed into our reinforced postal box, labelled in discreet packaging and a tamper proof seal is put on the package.

Our process of packaging provides the medication within a range of 2-8 degrees for up to 54 hours. The data supporting our choice of packaging is shown below [see graph at Appendix A]. The range remains within the 2-8C for the duration of that time.

The package is then sent using an approved MHRA registered cold chain courier (a choice of which are available to use depending on the size of delivery and the availability to deliver in the required time to the patient). All cold chain couriers approved by the RP will provide strict and stringent processes to ensure the viability of the cold chain is maintained from collection to transport and then to final delivery to the patient. On collection of the packages the courier signs receipt from the pharmacy. Once handed over, the pharmacy cold chain courier book is completed with the tracking numbers being put alongside the patient name and the individual item names.

Each approved courier meets regulatory standards and offer a specialist service in transporting pharmaceuticals. The couriers use refrigerated vehicles and have refrigerated storage at each point throughout the delivery process. From dispatch to final-mile delivery the cold chain couriers have a fully monitored and transparent service. Should any breaches occur, the cold chain couriers will notify the pharmacy and the RP will be informed. The relevant steps outlined below will then be taken and the patient contacted immediately by telephone to inform them of the breach and the steps which will take place to re-deliver new stock of the item.

At any stage of the delivery, the Responsible Pharmacist can ask for confirmation of the temperatures being maintained from the courier within the range and this can be audited throughout the delivery process. Post-delivery reports are also available to the pharmacy

Our processes have been designed to ensure end to end integrity of the cold chain and is designed to keep the patient informed throughout the process. We simplify and encourage communication to and from the patient with the pharmacy.

In the event of an unsuccessful delivery, the courier will leave a message for the patient, stating the date and time of the attempted delivery and a collection point or re-delivery options if this has been agreed with the patient in advance. The pharmacy can help rearrange delivery for a convenient time by telephone. All cold chain medication delivery confirmations are checked for delivery within 24 hours for signed receipt from the patient. If the package has not been signed for, the patient is contacted to confirm receipt and to support with any arrangements required.

Delivery Temperature Deviation Procedure

If it is found during delivery that the maximum/minimum thermometer readings are outside the ideal 8C and 2C and there is a concern that there has been a breach in the cold chain then this should be brought to the attention of the Responsible Pharmacist. In this event, please follow these procedures."

5.64 Paragraphs 3.114 and 3.115 state:

5.64.1 *"If the breach of the cold chain is discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review.*

In all instances, whether for local or national delivery or whether a cold chain or non-cold chain the pharmacy will always provide delivery estimates for delivery. This is done by the pharmacy updating the online portal as well as sending a text message to the patient. This information is always available if a patient calls the pharmacy. Should there be any delay in delivery then times are updated accordingly."

5.65 The Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

5.66 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting / measuring, a registered pharmacist measures / fits them. The Committee noted that on the application form the Applicant had not indicated that it wished to supply any appliances.

5.67 The Committee noted that at paragraphs 3.66 and 3.67 above, the Applicant states:

5.68 *"In the event that a prescription for an appliance which needs fitting is received from a patient, before ordering the medicine, pharmacy staff will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there is no change to the size that is needed.*

Receiving a New Appliance Prescription

In the event that there is a new prescription for an appliance which needs to be fitted, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will inform the patient that the pharmacy complies with the NHS Terms of Service and will;

if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist. In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care."

5.69 In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances to patients.

5.70 The Committee considered whether the Applicant had explained what containers will be suitable for posted / delivered items.

5.71 Paragraphs 3.84 – 3.86 above state:

5.71.1 *"The choice of packaging selected depends on the type and nature of the medication being packed.*

The packaging must be selected in accordance to stability, security and maintaining integrity of the item. On all occasions tamper proof seals must be added to the final package before leaving the pharmacy. For non-fragile items within the local delivery range can be sent in standard pharmacy paper bags. All boxes used in the delivery process at any stage must be reinforced cardboard boxes.

For postal items all are packed in reinforced cardboard boxes surrounded in bubble wrap to ensure integrity of the items and should any fragile items be sent then in addition to this filling material is to be used to restrict movement of the item. Additionally, for glass bottles for instance, items are packed in air filled pouches to protect the package."

5.72 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

5.73 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there have been no changes to the patient's health, which may indicate the desirability of review the patients treatment.

5.74 Paragraphs 3.135 – 3.142.2 state:

5.74.1 *"Patient Advice on Medication Use*

Dosage and Administration

Advise patients to follow the prescribed dosage and administration instructions.

Recommend the use of medication reminder tools (apps, pill organisers).

Storage Instructions

Inform patients about the correct storage conditions (e.g., cool, fridge, away from direct sunlight).

Emphasise the importance of keeping medications out of reach of children and pets.

Side Effects and Interactions

Explain common side effects and what to do if they occur.

Ask patients to inform the pharmacy of any other medications or supplements they are taking.

Patient Advice on Appliance Use

Assembly and Setup

Provide clear instructions for assembling and setting up appliances.

Offer remote assistance via videocall if patients encounter difficulties during setup.

Proper Use

Educate patients on the correct use of the appliance as per healthcare provider's instructions.

Stress the importance of maintaining a clean and hygienic environment.

Maintenance and Storage

Advise on regular cleaning and maintenance as per the manufacturer's guidelines.

Suggest appropriate storage solutions to ensure the appliance's longevity.

Providing Additional Support

Consultations

Offer remote consultations with pharmacists for personalised advice via telephone and videocall.

Ensure secure messaging services are available for patient enquiries.

Emergency Protocols

Provide patients with an emergency contact number for urgent medication-related queries.

Remind patients to contact emergency services in case of medical emergencies."

5.75 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

Further activities to be carried out in connection with the provision of dispensing services

5.76 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

5.77 Paragraphs 3.149 – 3.164 state:

5.77.1 *"Assessing a patient as to their need for a repeat prescription remotely.*

Repeat prescriptions will be dispensed as per our Dispensing of Prescriptions and Repeat Dispensing SOPs as per below with the addition of offering the service to patients for storing the documentation if required. An appropriate pharmacy record card will 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 will be recorded in the comment section of the pharmacy copy of the card.

Supply will only be made when medication is required and when no changes have occurred that would require referral back to the GP. Before any issuance of a repeated prescription, all patients are asked the following questions via the telephone or video consultation.

Did you experience any side effects from your last prescription?

Are you experiencing any issues with your last prescription?

Did your last prescription arrive at your delivery address damaged?

Have there been any changes to your health since the issuance of this prescription which would lead to you not requiring it?

Responding to a patient indicated need.

The Responsible Pharmacist will telephone/video call 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 the 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 will be recorded on the Intervention and Referral Form.

Identify a repeat dispensing co-ordinator for your pharmacy.

Whilst not a requirement for the implementation of repeat dispensing, the pathfinder sites have reported the benefits of identifying someone within your pharmacy, not necessarily the pharmacist, to co-ordinate the service.

Promote Repeat dispensing.

Promote eRD and identify suitable patients for the GP practice(s) as per Essential Service in Pharmacy Contract, by using the 'suitable for eRD' stamp. Contact the patient by phone.

Identify suitable patients.

Repeat dispensing will only suitable at this stage for people with stable long- term conditions and on 4 or less regular medicines who are likely to remain on the same medication for the duration of the batch issue

NHSBSA data will be provided to highlight patients suitable for the switch to eRD by NHS number for individual practices. Schedule 2 and 3 Controlled Drugs cannot be prescribed on eRD. Schedule 4 and 5 Controlled drugs can be prescribed, however, there are conditions for dispensing (GP/Senior PCN Pharmacist to authorise on a per-patient basis)

Unlicensed specials are not suitable for eRD

Medications requiring frequent review such as acute medicines, warfarin, methotrexate, lithium, DMARDs and benzodiazepines and hypnotics are not suitable for eRD Obtain consent remotely by phone or video.

Ensure there is a robust system for passing on messages from the practice to the pharmacist about monitoring requirements to avoid problems when the next repeat is requested.

Patients signing up to this service must consent to the sharing of the information between the pharmacy and GP surgery. Ensure that consent for the eRD and EPS has been appropriately recorded. This can be by telephone, email, videocall, post or by a message on the patient online platform. If patient changes their nominated pharmacy at any time their eRD prescriptions (including any remaining batches) will be issued to the newly nominated pharmacy.

Check items are needed.

Check and confirm with the patient by telephone or the agreed contact method what items the patient requires at each dispensing. Record any items not dispensed. All electronic messages from the GP must be sent to the patient via the online portal or they are printed and posted to the patient.

Receiving Prescriptions

The eRD will be automatically sent to the pharmacy or the patient may send the token by freepost.

The token can be used to retrieve the prescription from the NHS spine as per the PMR system's process. Check the repeatable prescription is not more than 6 months old or 28 days for Schedule 4 Controlled Drugs. Subsequent batch issues are valid for 12 months from the signed date. Print off the prescription, label and assemble the items following the appropriate SOP.

Final issue of a repeat.

Contact the patient by phone and inform patient when the final issue has been dispensed and advise them to contact the practice. Ensure all documents are used correctly stored as this will be helpful for audit purposes. A Claim Notification should be submitted to the NHS Spine as per PMR process."

5.78 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

5.79 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

5.80 Paragraphs 3.143 – 3.143.3 state:

5.80.1 *"Disposal Instructions*

Inform patients about local disposal guidelines for unused or expired medications as well as the availability for the pharmacy to collect unwanted medication from the patients home.

Guide patients on the proper disposal of appliances as per manufacturer's instructions.

Advise medication should not be disposed of in general waste and advise on the types of medication and types of disposal required."

5.81 Paragraphs 3.165 – 3.169 state:

5.81.1 *"For patients within the local driver radius who contact the pharmacy by telephone or the agreed contact method to arrange a collection as there is no face-to-face interaction with the pharmacy.*

Drivers collect the returned medication and store appropriately in the identified area in the pharmacy when returning and organised accordingly.

For requests for CD returns, the Responsible Pharmacist must be notified and arrange to speak directly to the patient. The name, strength and quantity to be returned must be ascertained and then the collection organised. On return to the pharmacy the driver must hand the controlled drug directly to the responsible Pharmacist who will then follow the GPhC guidelines on the destruction of controlled drugs. Controlled drug returns should not be mixed in the same area as stock and the separate CD cupboard allocated for returned CDs only. Destruction must be witnessed by an appropriate officer for the local area. The correct entry must then be made in the CD destruction book.

When collecting a returned medication from a patient not within a local collection area, a tracked Royal Mail collection is organised with the patient. The same procedure as mentioned above with regards to CDs should be followed.

The pharmacy cannot accept waste from nursing homes. The pharmacy cannot accept sharps or clinical waste. Local procedures should be advised as well as signposting to the most appropriate service. Returns from patients homes are collected via an approved NHS contractor, currently PHS. A collection note must be received on completion of the collection."

5.82 On the basis of the information provided, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 13-15 of Schedule 4.

Promotion of healthy lifestyles

5.83 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.

5.84 Paragraph 3.175 states:

5.84.1 *"If a non-electronic prescription or non-electronic repeatable prescription is presented to the pharmacy by post, the patient will be contacted via telephone or the preferred contact method. Upon consultation, if the pharmacist notices on clinical review that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face-to-face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through leaflets to be delivered to patients' home. Where advice is provided it should be recorded on the PMR. The email newsletter and website will also be used to promote a healthy lifestyle. Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage*

of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions."

5.85 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

5.86 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

5.87 Paragraph 3.175 states:

5.87.1 *"If a non-electronic prescription or non-electronic repeatable prescription is presented to the pharmacy by post, the patient will be contacted via telephone or the preferred contact method. Upon consultation, if the pharmacist notices on clinical review that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face-to-face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through leaflets to be delivered to patients' home. Where advice is provided it should be recorded on the PMR. The email newsletter and website will also be used to promote a healthy lifestyle. Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions."*

5.88 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

5.89 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by the Commissioner.

5.90 Paragraphs 3.177 - 3.181 state:

5.90.1 *"The Pharmacy will actively engage in national health campaigns to disseminate health messages to our patients throughout England. This will involve distributing leaflets along with prescriptions during targeted campaign periods and offering additional advice and educational materials through when requested by telephone or email. Patients will also receive information via emails regarding health campaigns throughout the year.*

Patients will receive guidance on accessing these learning resources via email, text messages, and other forms of non-face-to-face communication to ensure awareness of the campaigns.

Additionally, patients will be evaluated for participation in at least one clinical audit and any other audits specified by the NHSCB. These audits may include clinical audits conducted in accordance with NHSCB data processing arrangements or policy-based audits designed to support the development of NHSCB commissioning policies, all of which will comply with NHSCB data processing protocols.

These campaigns are recorded and the patients involved have a note added to their PMR with the specific details.

All information relating to NHS Essential Services will appear on the website which will be regularly updated to reflect current campaigns. The pharmacy is able to contact patients via email to confer public health campaigns."

5.91 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

5.92 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

5.93 Paragraphs 3.170 - 3.173 state:

5.93.1 *"Minimising inappropriate use of health and social care services*

Our pharmacy considers it the duty of any Responsible Pharmacist working for us to minimise inappropriate use of health and social care services and of support services as a day-to-day activity. All patients that cannot be provided with adequate help and support will be referred or signposted to other health and social care providers or support organisations who may be able to assist the person accordingly. Information can be provided by telephone, online or by posting available literature to the patient. Staff ask WWHAM questions by telephone or video consultation and when needed refer to the Responsible Pharmacist for further history taking.

Recording the referral

The pharmacist will make a note of the referral if deemed necessary and will provide a written referral note if required. Signposting will be carried out equally when approached either by email or on the phone. Where advice cannot be provided this should be recorded as an Intervention on the patient record along with the referral organisation. The pharmacy has a list of local services available and if the patient is not a local, then the pharmacy can assist them by pointing out those services closest to them through the NHS Choices website or the NHS 111 service if necessary. Focal Point also has links to main health topics to the NHS Choices website through the website."

5.94 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

5.95 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

5.96 Paragraphs 3.191 - 3.197 state:

5.96.1 *"There are a wide range of self-care support interventions. These have varying levels of intensity, differences in content, and a range of theoretical underpinnings (from didactic education to the use of behavioural counselling techniques and theories of behaviour change). The goal is to empower individuals with greater understanding of their treatment options and to reduce unnecessary utilisation of health and social care services.*

The advice provided encompasses:

Provision of advice to people, including carers, requesting helping with the treatment of minor illness and long-term conditions, including general information and advice on how to manage illness

Provision of advice on appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions

Provision of healthy lifestyle interventions when appropriate for promotion of healthy lifestyle service

Signpost patients to other health and social care providers when appropriate

Providing Self Care

We will endeavour to provide maximum support from the pharmacy to enable people to care for themselves or their families. There are a range of topics ranging from long-term conditions to minor ailments via our website which links to the NHS Choices website for up-to-date information and support and also if the patient would like more in-depth scientific knowledge about medication or health conditions. Self-care our pharmacy intends to provide to our patients include:

information-giving

addressing motivations and barriers to change

teaching coping strategies

designing action plans

dealing with emotional illness

ongoing monitoring/support

engaging family and social support

Opportunistic self-care

The support for self-care will also be provided opportunistically if a patient or carer telephones the pharmacy for advice or books a video consultation. A note will be made of any advice given to patients whether online or over the phone if deemed necessary. This service intertwines of course with signposting and public health promotion. A record should be made in the PMR."

5.97 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Discharge medicines service

5.98 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P 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 P 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.

5.99 Further the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.

5.100 Paragraphs 3.185 - 3.190.2 above state:

5.100.1 *"Patient Referrals*

Check appropriate IT systems for patient referrals - Agree suitable timings within day

Confirm minimum requirements of information have been provided on the referral (Appendix 2) and start the DMS Stage 1

If information is missing contact details of referring clinician/hospital department.

DMS - Stage 1 (Completed as soon as possible, but within 72hrs on receipt of referral) (*excludes hours of days when pharmacy not open)*

Check referral for clinical information and actions required

Check all previously ordered prescriptions for the patient (including any awaiting delivery is still appropriate.

Pay particular attention to electronic repeat dispensing prescriptions as may be pulled down from the NHS spine a while after patient has been discharged.

Compare post discharge list of medicines with those being taken before admission.

If necessary, raise any issues identified with the NHS Trust or Patient's GP, as appropriate.

Record notes as appropriate on the PMR system and/or other appropriate record.

Ensure flag in place on record to alert staff of the need to complete Stages 2 and 3, when o first prescription received, or

first contact with patient/carer

DMS - Stage 2 (Completed when 1st Prescription received following discharge, Usually with 1 week to 1 month following discharge)

Check medicines prescribed reflect appropriate changes made during the hospital discharge

Any discrepancies / issues to be raised with GP practice to try and resolve

Record notes as appropriate on the PMR system and/or other appropriate record.

DMS - Stage 3 (Remote confidential discussion with patient/carer on dispensing of this 1st prescription)

Conduct a confidential conversation with the patient / carer to check their understanding of the medicines. This is done via telephone / video call.

Adopting a 'shared decision making' approach to improve compliance / adherence

If any information discussed, is considered to be clinically appropriate to support patients' on going care, it should ideally be shared with patient's general practice/PCN pharmacy team

Gain patient consent to share, and record on notes.

Send notes using a secure method

If appropriate, offer to dispose of medicines no longer required by non face to face contact, to avoid any potential confusion.

Record notes as appropriate on the PMR system and/or other appropriate record.

All stages of DMR cannot be completed

If the above normal patient journey through the service cannot be complete

Pharmacist/pharmacy technician to use professional judgement to determine the appropriate actions to take. (see appendix 3 for details of examples)."

5.101 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

5.102 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

5.103 The Committee noted references to the website containing links to NHS Choices, being regularly updated with important information / messages, as well as being used to promote healthy lifestyles. The Committee also noted the website will contain information on a range of topics such as minor ailments.

5.104 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

5.105 On the information before it, the Committee could be satisfied that there are procedures likely to secure the safe and effective provision of essential services as required by Regulation 25(2)(b). However, for the reasons set out at paragraphs 5.32 and 5.33 above, the Committee could not be satisfied, as it is required to be, that the provision of services would be without interruption

5.106 The Committee therefore determined that it was required to refuse the application under Regulation 24(3)(d).

Overall

5.107 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:

5.107.1 confirm the Commissioner's decision;

5.107.2 quash the Commissioner's decision and redetermine the application;

5.107.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter back to the Commissioner.

5.108 As the Commissioner did not consider the application against all aspects of Regulation 24 or Regulation 31, the Committee determined that the decision of the Commissioner must be quashed.

5.109 The Committee went on to consider whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to remit the matter to the Commissioner) or whether it was preferable for the Committee to redetermine the application.

5.110 The Committee noted that representations on Regulation 24 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties who made representations on the application, as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 24.

5.111 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

6 **Decision**

6.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31

6.2 The Committee quashes the decision of the Commissioner and redetermines the application.

6.3 The Committee has determined that the conditions set out in Regulation 24(1) (a), (b), (c), (d) and (e) are satisfied.

6.4 The Committee has determined that it was required to refuse the application under Regulation 24(3)(d) after considering the grounds set out in Regulation 25.

6.5 The application is refused.

Technical Case Manager
Primary Care Appeals