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21 March 2024

REF: SHA/26136

APPEAL AGAINST WEST YORKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY MZS LOCUM LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 14, SHARP STREET, DEWSBURY, WF13 1QZ UNDER REGULATION 25

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:

MZS Locums Ltd
Community Pharmacy West Yorkshire
PCSE on behalf of West Yorkshire ICB

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1 The Application

By application dated 1 April 2023, MZS Locum Ltd ("the Applicant") applied to West Yorkshire ICB for inclusion in the pharmaceutical list at Unit 14, Sharp Street, Dewsbury, WF13 1QZ under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant stated

1.1.1 "All items Listed in Drug Tariff part IX EXCLUDING appliances which require measuring or fitting."

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:

1.2.1 "This is not applicable as the pharmacy is not in close proximity /adjacent to/in the same building to another pharmacy or dispensing appliance contractor."

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.3.1 "This is not applicable as the pharmacy is not in close proximity/adjacent to/in the same building to a provider of primary medical services with a patient list."

Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies

1.4 Please find below information to 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.

1.5 "7.1) – the proposed hours will be covered by myself/ employed pharmacist/ a locum pharmacist. This will ensure there is no disruption to the provision of essential services to persons anywhere in England who request those services.

1.6 I will ensure there is adequate staff on hand to deal with the work load and may have a regular locum pharmacist who cover a single day per week to ensure they know how the pharmacy operates and can help cover the pharmacy for holidays. As the business

grows, I will look to employ a pharmacy manager who can look after the pastoral side of the business and I can concentrate on the Clinical side myself.

1.7 I live locally to where I am planning on opening the pharmacy, so even in poor weather, I will be able to continue with my service provision. There will be contingencies in place for power cuts, software and hardware issues to ensure we continue to operate. SOPs will be put in place to ensure everyone is aware of what to do if this does happen.

1.8 I am planning on having the latest software available in the pharmacy market, which will help with the processing of prescriptions and also keeping the patients informed of the whereabout of their prescriptions. The software system I am looking at installing is Titan.

1.9 7.2) – there will be no face to face contact with anyone seeking essential services. Entry will be refused at the door and we will always be working behind closed doors. An intercom system may be deployed to determine a visitors reasons for coming and can be refused without face to face confrontation

1.10 If anyone does attend face to face seeking essential services, they will be refused and sent away. We will have a practice information leaflet available explaining our services which the patient can take away with them and sign up to our services in the comfort of their home.

1.11 There will be clear sign on the door which also states if they do not have an appointment, they will not be seen. Our number will also be written for them to contact us to discuss any of their medical needs. We will have a social media presence, that they can also reach us through.

1.12 7.3) If advanced services are offered at the premises, it will be made clear to the patient that they are only attending for the advanced service they have signed up for and nothing else. This will be done via an appointment system, so we know who is attending, when and what for. This will ensure staff are aware of who is expected on the premises. Any unplanned visits will be refused."

2 The Decision

West Yorkshire ICB ("the Commissioner") considered and decided to refuse the application. The decision letter dated 13 December 2023 states:

2.1 "West Yorkshire 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."

Extract from the decision report

2.2 "Re: Application for Distance Selling Premises by MZS Locum Ltd, Unit 14, Sharp Street Dewsbury, WF13 1QZ

2.3 The Pharmaceutical Services Regulations Committee (hereafter referred to as "the Committee") considers all pharmaceutical services applications on behalf of NHS England & NHS Improvement East of England in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as "the Regulations").

2.4 The Committee has now considered your application and I am writing to confirm that it has been rejected.

2.5 This application was considered under Regulation 25 (2) (a) & (b), Regulation 31 and Regulation 64 - which sets out the specific conditions to be met by applications for Distance Selling Premises.

2.6 The Committee considered Regulation 31 and agreed that this does not apply as there is no pharmacy at the same or adjacent premises to the proposed site.

2.7 The Committee then considered Regulation 25 and determined that it had not been fully met.

2.7.1 Regulation 25 (2) (a) it was confirmed this was not applicable as no primary care provider with a patient list is present within the same premises as the proposed site.

2.7.2 Regulation 25(2)(b) is not met as the applicant has not demonstrated how all services will be provided remotely, and without interruption throughout the given opening hours to persons anywhere in England who request those services.

2.8 Regulation 64 - Regulation 64 sets out the specific conditions to be met by applications for Distance Selling Premises:

2.8.1 The applicant must not offer to provide pharmaceutical services, other than directed services, to persons who are present or in the vicinity of the pharmacy premises.

2.8.2 The means by which persons receive services from the pharmacy must be otherwise than at the pharmacy premises.

2.8.3 The pharmacy premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.8.4 The pharmacy procedures must ensure the uninterrupted provision of essential services, during the pharmacy opening hours, to persons anywhere in England who request the services and must ensure the safe and effective provision of essential services without face-to-face contact between the person receiving the services and the pharmacy staff.

2.8.5 The pharmacy must not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.

2.9 Following consideration of the information provided by the applicant in the application form, the representations and the applicants response to the comments in the representations, the Committee rejected the application. In considering whether safe and effective provision of essential services was likely to be secured and considering essential services in paragraphs 3 of Schedule 4 of the Regulations (Terms of Service), the Committee noted that the applicant had provided limited information within the application form and that whilst the applicant had addressed comments made within the representations, providing additional information, the information provided still did not satisfactorily provide complete assurance that the specific conditions set out in Regulation 64 would be met in providing safe and effective essential services.

2.10 NHS England therefore rejected the application for Distance Selling Premises on the grounds that the applicant had not met the requirements set out in Regulation 25 and Regulation 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.11 Appeal rights are granted to:

2.11.1 The Applicant”

3 **The Appeal**

In an undated letter received by email on 11 January 2024 the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "Re: Application for Distance Selling Premises by MZS Locum Ltd, Unit 14, Sharp Street Dewsbury, WF13 1QZ

3.2 Thank you for your recent reply [sic] to my application for DSP. In order to give further depth to my answers in the application, I thoughts [sic] I could provide extracts from the SOPs we will be using to ensure the safe and effective provision of services. I have included titles of certain SOPs which would contain the extracts.

3.3 I am certain this will satisfy your criteria for Regulation 25(2)(b) and Regulation 64 being met.

Essential Services

3.4 We will be providing uninterrupted provision of essential services, during the allocated opening hours of the pharmacy practice, to persons anywhere in England who request those services. The provision of these services will be conducted without face to face contact with any member of the pharmacy team and those who are receiving the service for themselves or anyones behalf [sic], on or in the vicinity of the pharmacy premises. Face to face contact will only be permitted in provision of services other than Essential Services, this will be on an appointment only basis.

3.5 Essential services include:

Dispensing Medicines	Discharge Medicines Service	Health Living Pharmacy
Dispensing Appliances	Disposal of Unwanted medicines	Public Health
Repeat Dispensing & eRD	Signposting	Selfcare Support

3.6 All communications with patients for Essential services must be conducted through E-mail, phones, video conferencing, SMS.

3.7 All staff must be aware that we provided services to patients all over England and will not discriminate based on geographical location.

3.8 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, it clearly highlights the essential services and the rules pertaining to how this service will be provided to the patient i.e. non face to face contact and to all patients nationally)

Responsible pharmacist (RP):

3.9 As a distance selling pharmacy, we need to ensure a Responsible Pharmacist is available on site to ensure the uninterrupted service throughout the opening hours. If the RP has not turned up on the day or has left the premises before closing time, the superintendent needs to be informed immediately.

3.10 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, ensuring there is a pharmacist on site at all times during operational hours, ensuring uninterrupted provision of service).

Website

3.11 To remain active 24 hours per day, 365 days per year. Any down time must be reported to the superintendent so it can be rectified immediately. Website will be available nationally for anyone to access.

3.12 Patients can be directed to the website for the practice leaflet as well as the frequently asked questions tab, which will cover possible questions may have and will be regularly updated as new problems arise with time.

3.13 The website will be used to promote healthy lifestyle, payments and for patient recruitment

3.14 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, ensuring the website is available for access for all patients around the country and available at all times).

Dispensing of prescriptions

3.15 Prescriptions will be received primarily through EPS and processed through the computer system. On occasion we will collect and dispense non-EPS prescriptions, process any received through the post and any other requests we may receive the online contact us form. [sic].

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

3.17 If patients are on long term medications and the medical condition is stable, they would be informed of the repeat dispensing service and the benefits it can provide for them. Patient will be fully informed so they can engage with their surgery and ask for the relevant prescription issue.

Repeat Dispensing

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

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

3.18.2 Advise the patient that they should only order items that they need

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

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

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

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

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

3.18.8 Accurate records will be kept of all medications being issued each month and the RA of the prescription will be kept in a monthly/2monthly/3monthly filing system so the prescription can be processed in a timely manner on the next occasion

3.19 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, outlining a safe and effective dispensing process and also covering repeat dispensing which is going to improve patients access to medication and reduce workload for the GP surgeries)

Packaging

3.20 Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

3.21 All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

3.22 Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in using the pharmacy bags supplied for standard prescription items.

3.23 DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the reenforced boxes that are purchased for delivery purposes.

3.24 For postal items, either:

3.24.1 At the very least – padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

3.24.2 For most items – bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the enforced cardboard boxes**

3.24.3 Large or fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.

3.24.4 Cold chain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the “FRAGILE” and “FRIDGE LINE” stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box (“cold ship” packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range. Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used.

3.25 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, as it covers the procedure for packing the medication safely and preparing it for delivery)

Delivery of Medication

3.26 For items other than cold chain / “fridge line” items, local deliveries (up to 20 mile radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used or if the items are fridge lines, in which case the cold chain courier should be used.

3.27 When using the in house delivery driver, the following checks will take place:

3.27.1 Ensure that any special instructions for the delivery are included within the packaging.

3.27.2 Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.

3.27.3 Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.

3.27.4 Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

3.27.5 Ensure the delivery driver is notified of any messages for the patient or representative.

3.27.6 Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.

3.27.7 Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended.

3.28 When Royal mail is used

3.28.1 Follow preparation for delivery process. The pharmacist should contact any patients for whom there are relevant messages or counselling required.

3.28.2 Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.

3.28.3 Ensure a return address is printed clearly on the outer packaging. Confirm details of all prescriptions to be delivered.

3.28.4 Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.

3.28.5 Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery.

3.28.6 Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.

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

Delivery of Fridge Items:

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

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

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

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

3.30.3 A delivery should be booked using the couriers specified Cold Chain Services

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

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

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

Unsuccessful cold chain delivery via courier

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

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

Breach of Integrity of Cold Chain

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

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

Delivery of controlled drugs:

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

3.35.1 CDs should be in a separate bag to any other medication being delivered and the bags should be attached together

3.35.2 The delivery van must be kept locked at all times when the driver is not in the vehicle

3.35.3 The delivery driver/courier should sign the back of the prescription as the representative when accepting the CD for delivery

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

3.35.5 All entries in the CD register should be made when the medication leaves the pharmacy premises. The delivery driver/courier should be entered as the 'person collecting'

3.35.6 The prescription should be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier

Successful Schedule 2 & 3 Delivery

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

Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

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

Unsuccessful Schedule 2 & 3 Delivery via courier

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

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

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

3.41 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, outlines the different avenues for delivery for fridges and controlled drugs, as well the different couriers. Company delivery drivers that we will be using.)

Exemptions checks / Prescription Payments

3.42 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e. for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service) and the pharmacy can note that the evidence provided

was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

3.43 If the patient is to pay for the prescriptions, we will contact the patient to arrange payment using the secure payment system, ensuring the correct amount has been paid.

3.44 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, ensuring patients are not making fraudulent claims on the backs of their prescriptions and ensuring we are paid correctly by the NHS)

Patient returns of controlled drugs:

3.45 This service is available to all patients living in England.

3.46 Patients or their representatives may not return medicines directly to the pharmacy and must follow the set procedures.

3.47 Patients should be referred to the 'Returning unwanted medication' page on the website for information.

3.48 To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this should always be the pharmacist on duty.

3.49 The process for returning medication should be explained to the patient.

3.50 Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail.

Return with company driver

3.51 Drivers need to:

3.51.1 Be aware that they cannot accept patient returns from patients without prior arrangement. The driver should notify the patient to follow the "returning unwanted medication" process as set out on the website.

3.51.2 Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.

3.52 Accepting the return:

3.52.1 Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances.

3.52.2 Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal.

3.52.3 Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

3.52.4 Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

3.52.5 Identify any flammable waste and store separately until this can be removed by the waste contractor.

3.52.6 Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

3.52.7 Store returned medicines in the quarantine area of the van for transport.

3.52.8 The returnable items can be taken back to the pharmacy for destruction.

Controlled drug return Via Royal Mail

3.53 The pharmacist must:

3.53.1 Speak to the patient about the return and clarify the items being returned

3.53.2 Assess the items for suitability for return by Royal Mail

3.53.3 If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

3.53.4 Send the packaging to the patient along with the instructions for appropriate packing of the goods

3.53.5 Contact the patient to ensure that the package has been received

3.53.6 Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally

Disposal of medicine

3.54 Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

3.55 Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect.

3.56 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, as it clearly outlays the processes to dispose of patient returns safely, without the patient attending the pharmacy site during the operational hours of the pharmacy).

Discharge Medicine Service

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

DMS Stages

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

Additional advice, assistance and support

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

3.59.1 Summary Care Record Access - If appropriate, access the patient's Summary Care Record to see if it assists in providing the service

3.59.2 Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to;

3.59.3 Assess the patient / carer understanding of the medicines that the patient should be taking

3.59.4 The patient should have received a copy of the prescribed medication from the hospital which lists the medication you are taking. This must match the discharge prescription when written.

3.59.5 If changes have been made to the patient's medication regimen, clearly explain the changes.

3.59.6 Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall

3.59.7 Think about high risk medicines or those where the treatment is more complex and where extra advice and support should be provided – e.g. anticoagulants

3.59.8 Discuss common or expected side effects

3.59.9 Discuss the use of medication apps which can be downloaded and may help the patient stick to their treatment plan.

3.59.10 If injectables have been prescribed and the patient is considered to be able to self-administer these, then have they received appropriate training from their GP practice nurse or hospital?

3.60 Inform the patient / carer about:

3.61 The disposal service offered in respect of unwanted drugs (see separate SOP). This is particularly relevant to medicines which may still be in the patient's home but may no longer be prescribed.

3.62 Any other pharmaceutical services that the patient or their carer may benefit from following their stay in hospital and / or the transfer of care from another NHS pharmacy.

Follow up

3.63 Where you identify any areas of concern then to the extent it is appropriate to do so in your clinical judgement, contact the patient's GP to discuss the concerns and consider any appropriate action plan to deal with the concerns.

3.64 In every case it is important to keep and maintain records of the above discussions, concerns and actions taken as part of providing this service and these will also assist in service evaluation processes.

3.65 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, outlining the process for DMS done remotely without face to face contact with the patient or representative, ensuring continuity of care from the hospital and making sure patients questions are answered promptly post discharge.)

Promotional health

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

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

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

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

3.70 Patients will be identified during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

3.71 Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who requires advice, treatment or support that we cannot provide; but we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

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

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

3.74 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, participating in health campaigns without seeing patients face to face and ensuring they have access to all the information they need)

Self care

3.75 Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.

3.76 Advice should be backed up, as appropriate, by the provision of written material such as leaflets. When such a request is received, the pharmacist should be informed and a record kept of the request. Advice (and requests for advice) must operate without face-to face interaction (e.g. telephone, Live video, via the website).

3.77 (As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, outlining how we will provide support and education to patients for self care without face to face contact.)

3.78 I have been an exemplar Pharmacist for 13 years now and I know I will improve patient care and provide a safe environment for my colleagues to thrive in. I am constantly striving to improve myself and I see this as a natural progression in my career. I have been working in primary care for a decade now and my clinical knowledge has significantly been boosted because of it and I know I will change the way patients see their care given by a pharmacy.

3.79 Thank you for your consideration in this matter."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "Thank you for sharing representations received in response to this appeal and further detail as to how they will comply. We would like to take this opportunity to make any final observation(s). [sic]

4.1.2 West Yorkshire ICB (WY ICB) refused the application for a Distance Selling Premises on the grounds that the applicant had not met the requirements set out in Regulation 25 and Regulation 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.3 As per the notes of the PSRC (November 2023), the committee considered all the objections/representations provided and that despite comments made in respect of the applicant's further comments, in considering whether safe and effective provision of essential services was likely to be secured and considering essential services in paragraphs 3 of Schedule 4 of the Regulations (Terms of Service), the Committee was of the opinion that there was not enough evidence to be wholly satisfied this would be met.

4.1.1 Based on the original application and information provided at the time WY ICB is still satisfied that the correct decision was reached in relation to this application and would therefore ask that the appeal be dismissed."

4.2 COMMUNITY PHARMACY WEST YORKSHIRE

4.2.1 "Thank you for your letter dated 18th January 2024 concerning the above application.

4.2.2 Community Pharmacy West Yorkshire members still feel that their comments made in their letter to [the Commissioner] on 8th August 2023 are valid. These were as follows.

4.2.2.1 In considering this application members were mindful of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.2.2.2 They have asked me to make the following comments:

4.2.2.2.1 NHS England must be assured that Regulations 25(2)(a) and 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 do not apply.

4.2.2.2.2The applicant must give NHS England assurance that they will be able to provide pharmaceutical services throughout the contracted hours.

4.2.2.2.3NHS England will be aware of the decision made by NHS Resolution with regard to the Pharmacy 2 U (P2U) application in Leicestershire (SHA/22233). CPWY are sure that NHS England will want to reflect on the this application is not subject to the same or similar concerns. [sic]

4.2.2.2.4NHS England makes reference to previous applications for Distance-Selling pharmacies that have been refused upon appeal including the West Yorkshire applications SHA/18299 - May 2016 and SHA/18727 - Sept 2017.

4.2.3 Members wish these comments to be taken in to consideration by the Authority and wish to be notified of the decision."

5 **Summary of Observations**

This is summary of observations received.

5.1 THE APPLICANT

5.1.1 "Thank you for your recent emails regarding my appeal. I made several points which highlighted how I will meet the Regulations 25 & 64 in my recent appeal. I am confident I covered the criteria which NHS England will be looking for.

5.1.2 In my last letter I covered the Essential services and the protocols we will be following as an organisation to ensure safe and effective delivery of the Essential services.

5.1.3 I note the NHS West Yorkshire Integrated Care Board have stated in their last paragraph that "based on the original application and information provided at the time WY ICB is still satisfied that the correct decision was reached" clearly showing that they have not taken into consideration the subsequent evidence I have provided to supplement the application.

5.1.4 I would also like to highlight the comments made by representative of Community pharmacy West Yorkshire, effectively repeating their original comments about the application and not taking into consideration the subsequent evidence provided.

5.1.1 I look forward to hearing from you."

6 **Consideration**

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

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

6.3 The Committee noted the comments from Community Pharmacy West Yorkshire with regard to previous decisions which have been made by both NHS England and NHS Resolution whereby applications for distance selling pharmacies had been refused. Whilst the Committee was aware of previous decisions, it was also mindful that each decision is considered on its own merits. The Committee proceeded to consider the instant application based on the information before it which was provided by the Applicant in its application form and subsequent appeal.

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

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

Regulation 31

6.6 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) the NHSCB 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).

6.7 The Committee noted that the Applicant had stated "this is not applicable as the pharmacy is not in close proximity/adjacent to/in the same building to another pharmacy or dispensing appliance contractor" in response to why the application should not be refused under the provisions of Regulation 31. The Committee noted that the Commissioner had considered Regulation 31 and determined that there was no requirement to refuse the application under this Regulation. This had not been disputed by any party either or appeal or in subsequent representations. Based on the information before it, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.8 The Committee had regard to Regulation 25 of the Regulations which reads as follows:

"(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) The NHSCB 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

(b) unless the NHSCB 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."

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

Additional information to be included with excepted applications

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 the NHSCB in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.*

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

6.10.1 confirm the Commissioner's decision;

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

6.10.3 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 to the Commissioner.

Regulation 25(1)

6.11 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and paragraph (1)(a) 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)

6.12 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "This is not applicable as the pharmacy is not in

close proximity/adjacent to.in the same building to a provider of primary medical services with a patient list." The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied 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)

6.13 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.

6.14 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.

6.15 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 the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

6.16 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 supporting information which the Applicant included as part of their appeal.

6.17 The Committee noted that whilst the Applicant had made reference to their SOPs, these had not been provided as part of the application or subsequent appeal. The Committee was mindful that there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations. 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.

6.18 The Committee considered if the Applicant had shown that essential services would be provided on an uninterrupted basis.

6.19 The Committee noted the comment from the Applicant in their application that “the proposed hours will be covered by myself/ employed pharmacist/ a locum pharmacist. This will ensure there is no disruption to the provision of essential services to persons anywhere in England who request those services.”

6.20 The Applicant went on to state that they “… may have a regular locum pharmacist who cover a single day per week to ensure they know how the pharmacy operates…”

6.21 In their appeal, the Applicant expanded upon this and stated, under the heading “Responsible Pharmist (RP)”:

6.21.1 “*As a distance selling pharmacy, we need to ensure a Responsible Pharmacist is available on site to ensure the uninterrupted service throughout the opening hours. If the RP has not turned up on the day or has left the premises before closing time, the superintendent needs to be informed immediately.*

(As you can see this SOP will cover the needs of Regulation 25(2)(b) and Regulation 64, ensuring there is a pharmacist on site at all times during operational hours, ensuring uninterrupted provision of service)."

6.22 Whilst the Committee noted that the superintendent pharmacist would be informed that the RP had left the premises or not turned up, the Applicant had not described how the pharmacy would ensure there was no interruption to services during the core hours should the pharmacist be called away or not arrive as expected.

6.23 Based on the information provided to it, the Committee was not satisfied that the provision of services would be without interruption.

6.24 The Committee considered if the Applicant had shown that essential services would be provided across England.

6.25 The Committee noted the assurance from the Applicant in their appeal that they would be providing essential services to persons anywhere in England who request those services. Further the Applicant states "All staff must be aware that we provided services to patients all over England and will not discriminate based on geographical location". The Committee was of the view that this was further demonstrated on appeal by the Applicant's use of not only a local delivery driver but the use of Royal Mail and couriers for controlled drugs and specialised couriers for fridge lines.

6.26 There was nothing to conclude that the Applicant would not be providing essential services to persons anywhere in England. On the basis of the information provided, the Committee was satisfied that the provision of services would be available to persons anywhere in England.

6.27 The Committee considered whether the Applicant's provision of essential services would be without face to face contact.

6.28 The Committee noted the comments from the Applicant in their application form that "Entry will be refused at the door and we will always be working behind closed doors. An intercom system may be deployed …" The Applicant went on to say that anyone attending face to face seeking essential services will be refused and sent away. Further, there will be a clear sign on the door advising that if a patient does not have an appointment they will not be seen. The Committee inferred that this comment related to non-essential or private pharmaceutical services.

6.29 The Committee noted that this was reiterated in the appeal when the Applicant advises that all communication for essential services will be through email, phones, video conferencing and SMS and that there will be no face to face contact for the provision of essential services.

6.30 There was nothing in the information provided which would lead the Committee to conclude that essential services would be provided face to face.

6.31 The Committee was satisfied that the provision of essential services would be without face to face contact.

6.32 The Committee was aware that, when the pharmacy opens, 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.

6.33 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. However the Committee was of the view that the Applicant had not demonstrated that the provision of services would be without interruption. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

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

6.35 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:

6.35.1 Dispensing of drugs and appliances

6.35.2 Urgent supply without a prescription

6.35.3 Preliminary matters before providing ordered drugs or appliances

6.35.4 Providing ordered drugs or appliances

6.35.5 Refusal to provide drugs or appliances ordered

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

6.35.7 Disposal service in respect of unwanted drugs

6.35.8 Promotion of healthy lifestyles

6.35.9 Prescription linked intervention

6.35.10 Health campaigns

6.35.11 Signposting

6.35.12 Support for self-care

6.35.13 Discharge medicines service

6.35.14 Websites and health promotion zones

6.36 The Committee was of the opinion that the procedures adopted by the pharmacy were not likely to secure the safe and effective provision by the Applicant of the following essential services:

Urgent Supply without a prescription

6.37 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.

6.38 The Committee noted that there was no reference in any of the supporting information provided by the Applicant either in the original application form or on appeal that dealt with Urgent Supply without a prescription.

6.39 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

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

6.40 The Committee considered if the Applicant had indicated how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has a 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.

6.41 The Committee noted the reference in the appeal that:

6.41.1 "*If patients are on long term medications and the medical condition is stable, they would be informed of the repeat dispensing service and the benefits it can provide for them. Patient will be fully informed so they can engage with their surgery and ask for the relevant prescription issue."*

6.42 Further the Applicant had stated:

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

6.43 Whilst the Committee noted the references in the appeal to repeat dispensing as well as the paragraphs highlighted above, it was of the view that there was not sufficient information provided which demonstrated how the Applicant would promote the benefits of this service or how they would identify the patients who might benefit from this service who were not already in receipt of repeat dispensing.

6.44 The Committee was therefore not satisfied that it had been provided with sufficient information to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

6.45 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.

6.46 The Committee noted, in their appeal, the Applicant had stated that patients could return their medication with the company driver as well as by Royal Mail.

6.47 In respect of return by Royal Mail the Applicant stated:

6.47.1 "*Controlled drug return via Royal Mail:*

The pharmacist must:

Speak to the patient about the return and clarify the items being returned

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return …"

6.48 Whilst the Committee noted the comments from the Applicant with regard to returns via Royal Mail there was no information provided as to how those items which are not deemed suitable for return by Royal Mail would be returned to the pharmacy.

6.49 Therefore in these circumstances the Committee could not be satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13-15 of Schedule 4.

6.50 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Other considerations

6.51 The Committee noted that the Applicant was proposing to offer all items listed in the Drug Tariff part IX excluding those appliances which require measuring or fitting. The Applicant, in their appeal had confirmed this and reiterated that they would not be providing any appliances which required measuring or fitting and would signpost patients requiring these services to other providers in their area. The Committee was of the view that if the application was granted the Applicant would not therefore be able to provide these appliances as listed in the application form, to patients. Based on the information provided, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4

Summary

6.52 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

6.53 The Committee noted that whilst it had reached the same overall decision as the Commissioner, it had done so for different reasons. The Committee therefore determined that the decision of the Commissioner must be quashed.

6.54 The Committee considered 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 quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

6.55 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties 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 25.

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises

7.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list,

7.2.2.3 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours,

7.2.2.4 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England,

7.2.2.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,

7.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact;

7.2.3 The application is refused.

Case Manager
Primary Care Appeals