NHS Resolution

25 April 2024

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REF: SHA/26150

APPEAL AGAINST WEST YORKSHIRE ICB DECISION TO GRANT AN APPLICATION BY HEALTHCARE TIME LIMITED FOR A RELOCATION THAT DOES NOT RESULT IN A SIGNIFICANT CHANGE TO PHARMACEUTICAL SERVICES PROVISION UNDER REGULATION 24 FROM 27 NEWMARKET STREET, SKIPTON, BD23 2JE TO UNIT 6, CROWN WORKS, BRADFORD ROAD, SANDBEDS, KEIGHLEY, BD20 5LN

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 granted.

A copy of this decision is being sent to:

Temple Bright on behalf of Healthcare Time Limited
Rushport Advisory LLP on behalf of Crossflatts Pharmacy
Community Pharmacy West Yorkshire
PCSE on behalf of West Yorkshire ICB

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1 The Application

By application dated 24 June 2023, Healthcare Time Ltd ("the Applicant") applied to West Yorkshire ICB ("the Commissioner") for a relocation that does not result in a significant change to pharmaceutical services provision under Regulation 24 from 27 Newmarket Street, Skipton, BD23 2JE to Unit 6, Crown Works, Bradford Road, Sandbeds, Keighley, BD20 5LN. In support of the application it was stated:

1.1 "Application to relocate premises from the pharmaceutical list for North Yorkshire Health and Well-being Board's (HWB) area to the pharmaceutical list for Bradford HWB's area."

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

1.3 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this blank.

Information in support of application

1.4 "The pharmacy which is the subject of this relocation application is a distance selling pharmacy. Currently the pharmacy provides essential services from the listed premises. The current pharmacy premises does not have adequate space for a consultation room and also carries out NMS services remotely via video/telephone facilities as per regulations and will continue to offer this service uninterrupted to all patient groups after the move to the new premises.

1.5 In accordance with regulation 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, patients who receive essential services from the listed premises do so otherwise than whilst present at the premises.

1.6 No patient visits the premises in order to access pharmaceutical services.

1.7 Patients therefore receive pharmaceutical services from the listed premises remotely (for example through the electronic transfer of prescriptions, delivery arrangements, the postal service, and electronically by email, telephone and website).

1.8 Since there are no patients who receive pharmaceutical services "at the existing premises", for the purposes of regulation 24(1)(a), there are no 'patient groups' who are 'accustomed to accessing pharmaceutical services at the existing premises'.

1.9 Regulation 24(1)(a) does not, therefore, apply to the determination of this application. The pharmacy will continue to provide pharmaceutical services remotely and in accordance with regulation 64 following the proposed relocation, such that the pharmacy's patients will be entirely unaffected by the proposed relocation.

1.10 As a distance-selling pharmacy, we provide services to persons anywhere in England, rather than just within the area of the local HWB. Our service provision will be unchanged by the proposed relocation and, consequently, will not result in a significant change in arrangements for the provision of pharmaceutical services within the HWB area.

1.11 We are not aware of any plans by the HWB to which any detriment would be caused by the granting of this application."

1.12 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".

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

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

1.15 In response to "In my/our view this application should not be refused pursuant to Regulation 25(2)a) for the following reasons:" the Applicant left this blank.

1.16 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."

1.17 The Applicant stated "The answer to this question is attached with the application email as a file named 'Please explain how the pharmacy procedures used final'".

1.18 "A previous application with reference number ME1866 was approved by NHS England on 20/12/2022, this subsequently went to NHS resolution for determination due to an appeal by a third-party pharmacy. Appeal case reference for NHS resolution was SHA/25839. A decision declining the approval of the application was communicated to us on 27/04/2023. After careful consideration of the points raised by NHS Resolution, we have provided additional information with this application which addresses the concerns raised by NHS Resolution.

1.19 The answer to (a) and (b) above is as follows, and according to the regulatory requirements for distance selling pharmacies of NHS regulations 25 and 64 as well the guidance of the General Pharmaceutical Council:

1.20 The pharmacy is simply moving to a neighbouring HWB. This means that all of the current provisions, policies and procedures including SOPs will remain in place after

the move and indefinitely. The current provisions, policies and procedures satisfy all the regulations in relation to this application and will continue to do so after the move has been completed. We are not aware of any concerns or complaints in relation to the way in which pharmaceutical services have been provided to date. This should satisfy NHS England that the pharmacy is operating safely and effectively and is providing services in accordance with the Terms of Service.

1.21 There will be no interruption to the services which this pharmacy provides. The superintendent reviews the SOPs at least every two years and also continuously keeps policies and procedures of the pharmacy up to date in relation to any new legislation or guidance issued by the GPhC and NHS England.

1.22 The pharmacy also operates an up-to-date website which complies with all regulations, including GDPR. The pharmacy also complies with all of the relevant guidance for registered pharmacies by the GPhC issued in March 2022 in relation to providing pharmaceutical services at a distance.

1.23 The pharmacy will continue to provide essential services to any persons in England without face-to-face contact through the use of suppliers, couriers and service providers which are approved and operate in accordance with all regulations including cold chain and controlled drug requirements and also satisfy the SOPs and requirements of the pharmacy.

1.24 A Responsible Pharmacist is present and in charge during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients who live anywhere in England who require and request the essential services. Where necessary locum cover is arranged through the Applicant’s extensive network of pharmacist colleagues and through locum agencies. This ensures that the Pharmacy always has a responsible pharmacist signed in and present during its contracted opening hours. Locums are given instruction and training via shared SOP access prior to their shift. There is also a locum folder in the pharmacy which details all of the pharmacy’s procedures to ensure effective cover is in place.

1.25 Two supporting pharmacy staff are currently employed; if and when required, more staff will be hired to aid the Responsible Pharmacist in his/her role of uninterrupted provision.

1.26 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 are and will continue to be provided as follows:

Website:

1.27 The website which can be reached on www.timepharmacy.co.uk has been designed by a digital marketing company which specialises in the UK pharmacy sector called Pharmacy Mentor. It has been tailor made to ensure complete compliance with all requirements of a distance selling pharmacy website. The website is completely secure and follows the management guidelines and the law on data protection. The website uses secure methods for collecting, using and storing patient details. The website is kept fully up to date complying with the latest regulation, advice and GPhC guidance on websites.

1.28 The website displays the following:

1.28.1 Name of Superintendent, Pharmacy and Owner of Pharmacy: Nur Saleem, Time Pharmacy, Healthcare Time LTD

1.28.2 Name and address of registered pharmacy where medicines are prepared, assembled, dispensed, labelled and delivered from to patients: Crete House, 27 Newmarket Street, Skipton, BD23 2JE, United Kingdom

1.28.3 Links for information about how to check the registration status of the pharmacy and the superintendent pharmacist.

1.28.4 Email address info@timepharmacy.co.uk and phone number of pharmacy 01756 228280.

1.28.5 A services page displaying information about services the pharmacy offers and how to access them at https://timepharmacy.co.uk/services/.

1.28.6 Information on Return of medicines at https://timepharmacy.co.uk/delivery-and-returns/.

1.28.7 Patient life style questionnaire at https://timepharmacy.co.uk/lifestyle-survey/.

1.28.8 Promotion of Health lifestyles and campaigns via a health promotion zone at https://timepharmacy.co.uk/health-promotion-zone/.

1.28.9 Emergency supply method at https://timepharmacy.co.uk/emergency-supplies/

1.28.10 Annual patient Survey at https://timepharmacy.co.uk/annual-patient-surveys/

1.28.11 Complaints at https://timepharmacy.co.uk/complaints/

1.28.12 Feed back and contact at https://timepharmacy.co.uk/contact/

1.28.13 Medicines are currently not sold online. If it any point this changes all regulations in relation to sales of medicines online will be followed.

1.28.14 Register for exemptions from NHS charges.

1.28.15 Sign up page with information, confirmation and consents for delivery including use of safe places and their exclusions: https://timepharmacy.co.uk/sign-up/

1.28.16 An faq page for common questions: https://timepharmacy.co.uk/faq/

1.29 The pharmacy provides the public with access to pharmaceutical services from the pharmacy premises through the website www.timepharmacy.co.uk which includes an interactive page (https://timepharmacy.co.uk/health-promotion-zone/) that is clearly promoted to any user of the website when they first access it, this provides the public with access to a reasonable range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues. This is a new requirement under the Regulations that does not allow for face-to-face access to essential pharmaceutical services at the premises and only applies to access via the website.

1.30 The pharmacy has a practice leaflet which provides information about the services available from the pharmacy and makes it clear that services can only be provided remotely (ie without face-to-face contact with patients on, or in the vicinity of, the pharmacy).

Dispensing:

1.31 Dispensing services are provided as per the NHS Terms of Service. All the steps are carried out in accordance with the pharmacy Standard Operating Procedures (SOPs).

1.32 Prescriptions are received at the pharmacy by post via the use of pre-paid envelopes and via ETP/EPS through patient nominations which are requested by the patients directly via the surgery, our website, Healthera app or telephone.

1.33 Prescriptions are checked for legal and clinical appropriateness and dispensed accordingly by or under the supervision of a pharmacist. The pharmacy may refuse to supply a drug in the circumstances set out in the Terms of Service and will provide the patient with appropriate advice (by telephone, email, live chat via WhatsApp and video calls) as required.

1.34 Procedures are in place to ensure the Responsible Pharmacist can consult and advise the patient appropriately if the need arises, with the condition of non-face to face contact. This includes, where necessary, advising the patient on how long it will take for the prescribed medication to be delivered, to enable the patient to utilise the medicines appropriately, to provide general information about the prescribed medication, the safe keeping of the prescribed medication and the returning of unwanted medicines to the pharmacy for safe destruction. Contact with the patient is made via email, telephone, live chat via WhatsApp, video calls, leaflets and notes. Appropriate records are kept on the pharmacy's PMR regarding supplies and advice given.

1.35 Prescription charges are made via 3 secure methods which are invoice bank transfer or by phone using a credit/debit card or for local deliveries via handheld mobile card machine. Exemptions from payments are clarified by:

1.35.1 Phoning patients and asking about the type of exemption, the card exemption number and the date of expiry:

1.35.2 Collecting their exemption type on the online nomination form they fill out

1.35.3 Additionally, seeking evidence of the exemption where appropriate to do so (such as a photocopy of the exemption card); and also

1.35.4 Recording the exemption information given on the PMR system

1.36 Emergency supplies are carried out at the request of the prescriber. The RP has to be satisfied that there is a genuine reason why a prescription cannot be immediately sent to the pharmacy. The Prescriber has to furnish a prescription within 72 hours and the medication is supplied according to the prescriber's instructions. Schedule 1,2 & 3 medications cannot be requested. After the supply is made an entry into the prescriptions book stored on Pharm smart software is made.

1.37 Where a prescribed medication is subject to a Serious Shortage Protocol or a request for supply is made in accordance with a Pandemic Treatment Protocol or LPIV, supplies are made in accordance with the relevant SSP or PTP/LPIV.

1.38 Where Serious Shortage Protocols (SSP) has been issued, medicines not available or in short supply by the manufacturer, the SSP is followed to provide an alternative under the protocol. The patient is contacted via telephone to ensure they understand the change and ensure the patient knows how to use their medicine correctly. The patient is also informed of what to do if they experience any problems with the alternative medicine. Finally, the patient's GP is also informed of any adjustments made under the SSP. Prescriptions are endorsed accordingly and the prescriber notified.

1.39 Owings of medicines are dealt with in line with our procedures. Where manufacturers cannot supply medicines, the patient is contacted and the PMR (patient medication record) updated with information of any owings. An owing note is attached to the delivery to ensure the patient is informed about the owing items and of the expected date of delivery.

1.40 Where long term supply issues are apparent, after exhausting all possibilities of obtaining a certain medicine, either the patient is informed to enable them to contact their GP or the pharmacy contacts the patient's GP on their behalf with informed consent from the patient, for an alternative. The option of using another pharmacy, which has the medicine in stock is also presented to the patient, and the prescription is returned to the patient if needed, or in the case of EPS release 2 tokens, the prescription is returned to the spine and the patient is informed of any details they need to obtain their medicines from the pharmacy of choice.

1.41 All dispensed items are delivered by Royal Mail, a courier service or by a designated staff member depending upon the nature of the item and the patient's address to ensure delivery to patients anywhere in England. Deliveries comply with the GPhC guidelines of medicines delivery.

1.42 In regards [sic] to choice of delivery method, for local deliveries (up to 30-mile radius, but may be extended at the discretion of the RP) the delivery driver can deliver the medication. For local deliveries the delivery driver texts/emails the patients a definitive time period e.g., afternoon and date of delivery. The driver has access to the patient's delivery preferences as they are listed on the delivery label/pharmdel app. If a patient has a safe place or request to leave with a neighbour set as a confirmed and consented delivery preference prior to any delivery leaving the premises, we try our utmost to honour these preferences but make the patient fully aware that it may not be possible in certain circumstances such as delivery of controlled/fridge drugs. All deliveries are subjected to a robust audit system.

1.43 Local deliveries made by the delivery driver are tracked via a cloud/app based software system called Pharmdel. All local deliveries are scanned into the system via an app through integrated PMR barcodes. The driver scans these barcodes and confirms patient details with the patient/representative at the point of delivery, the software also records geolocation tags, photographs, time of delivery, signatures, failed deliveries and safeplace deliveries. The software meets all legal, GDPR and security requirements for handling patient data. All delivery preferences consented and agreed with the patient are also saved onto the system and only allow the driver to deliver within the legal parameters set by the pharmacy and agreed with the patient for example the system does not allow delivery of CDs without the patient or nominated representatives signature. These are accessible and checked by the RP daily via audit reports including CD delivery audit on the Pharmdel website dashboard. Local delivery staff are fully trained using accredited courses and company materials to ensure safe and effective deliveries.

1.44 Local cold chain deliveries involve the use of a calibrated portable medical fridge in conjunction with a built-in digital temperature logger and a standalone remote connectivity enabled cloud based calibrated digital temperature logger to ensure cold chain compliance by maintaining and monitoring temperature between 2 and 8 degrees Celsius. The portable fridge is not designed to be constantly in use, therefore it is plugged into the local power supply at the pharmacy an hour before the delivery drivers' route is expected to begin in line with the manufacturer's instructions, to allow it to reach the correct temperature range. The range is then checked via the built in temperature logger (max, min and current temperature) and recorded by the RP onto the Pharmsmart software under the portable fridge log to ensure that the correct temperature of between 2 and 8 degrees Celsius is being maintained.

1.45 All cold chain deliveries are prioritised during the route making process. As with all local deliveries the patient is informed via text/email of the date and time of day the delivery driver will be delivering. Particularly in regards to deliveries involving cold chain items the driver rings the patient to inform/confirm the estimated date and time of delivery before the medication is taken on the route to reduce the chance of delivery failure.

1.46 When the delivery driver is ready to leave on his route, cold chain items are added to the portable fridge. The standalone remote connectivity enabled cloud based calibrated

digital logger is attached and its probe added to the fridge at this point. This particular logger records and uploads temperature data continuously to a cloud-based web service, giving a complete record of cold chain monitoring for the full duration of the delivery process from start to finish. The portable fridge is unplugged from the local power source, taken to the vehicle and immediately plugged into the car's power source, temperature on the fridge's built in temperature logger is rechecked and recorded onto pharmsmart online log sheet by the driver. The driver also checks and logs the portable fridge temperature (max, min and current) onto the pharmsmart online log sheet via the fridge's built in temperature logger, every time he makes a cold chain delivery during his route which is reviewed by the RP at the end of the route in conjunction with the continuous data received from the standalone remote connectivity logger.

1.47 Both the built in and standalone temperature loggers have audible alarms for any range breaches. For an added layer of security, the standalone remote connectivity cloud based calibrated data logger also provides breach alerts via remote connectivity (text messages/ email updates) to the driver and pharmacy mobiles and emails.

1.48 In case of a breach the driver rings and informs the RP and returns to the pharmacy.

1.49 The RP then gains advice from the manufacturers of the items in regards to the nature length of the breach, segregates the affected items if necessary to avoid them being used by mistake, patients are informed and new items dispensed and a new delivery organised.

1.50 If a local cold-chain delivery fails due to the patient not being available to accept it, the driver simply brings the medication back maintaining cold chain in the portable fridge and returns the item to the 'awaiting delivery section' of the pharmacy fridge and consequently re-organises delivery for a more convenient date/time with the patient. At the end of every delivery shift, the fridge is returned and checked for damage. The entire process maintains cold chain from end to end, is effective, has a clear audit trail and allows the RP and driver to have complete oversight.

1.51 All non-local deliveries (except for cold chain products) are made by Royal Mail and are audited via information stored on the Royal Mail website with information such as signatures, geolocation tags, photographs, time and date of deliveries. All deliveries sent in this manner are checked by the team to ensure that deliveries have been received successfully.

1.52 Choice of packaging is subject to the type of the items and type of delivery. Our packaging has correct levels of protections to ensure item integrity and ability to withstand delivery processes. We attach tamper proof seals to our packaging to ensure that when the patient receives the package, they can be confident that it has not been tampered with.

1.53 For non-fragile local deliveries, we package using pharmacy bags supplied for standard prescription items. For fragile items we use sealable bubble wrap pouches which are then packaged into re-enforced heavy duty cardboard boxes. Fragile stickers are added to make the driver aware so he can handle the package with extra care. CD stickers are added to all CD items which are packaged individually into the standard pharmacy bags with tamper proof seals and kept in the cabinet. For Local Fridge items, items are placed into plastic pouches, post delivery storage condition instructions are added to the pouches and tamper proof seals and fridge item stickers are added. These are then stored in the awaiting delivery section of the fridge in the pharmacy till they are ready to be moved to the portable fridge prior to the delivery round.

1.54 For non-local Cold-Chain items, the item/items are placed in bubble wrapped pouches and any instructions on storage conditions post-delivery for the patients to follow are also added to the pouch. This is then placed into to [sic] the Styrofoam filled re-enforced cardboard boxes, fridge line and fragile stickers are attached to the outside of the box.

The box is then stored in the awaiting delivery section of the pharmacy fridge till it is handed over to cold chain courier. The cold chain company ensures the cold chain integrity from end to end by maintaining a range of 2 to 8 degrees Celsius. The company uses fully monitored vans and warehouses with cold chain sections to protect the integrity of the box/boxes and its contents to ensure it reaches the patient without any breach. All of our staff which handle the packaging of cold chain items are fully trained and understand that thermolabile products can get damaged from excessive temperatures both hot and cold.

1.55 For postal items - All of our packaging is completely discreet and of the highest quality and is selected to fit the type of medication posted.

1.56 Non-Fragile items - Heavy duty Padded bubble lined envelopes of different sizes are used dependent on the number of items that need to be posted to ensure manufacturers packaging integrity. If the items cannot fit into padded bubble envelopes, then we use a combination of bubble wrap around the items with cardboard protecting matting filler or biodegradable loose fill chips within re-enforced heavy duty cardboard boxes.

1.57 Fragile items - All large or fragile medicines such as creams/bottles are packaged with a combination of bubble wrap around the items either in a pouch format or loose bubble wrap. These are then placed into heavy duty re-enforced cardboard boxes and the voids are filled with cardboard protecting matting filler or biodegradable loose fill chips to protect during transit. Fragile stickers are added to the outside of the boxes to make the courier handle the package with extra care.

1.58 For Royal Mail deliveries the staff text/email the patients advising how their medication has been packaged and what exact service their package has been dispatched with. Large letters format can fit through letter boxes, parcels can be left (if confirmed and consented by the patient prior to any delivery leaving the premises) with neighbours/safe places (not applicable to CDs) if patients are not in, or re-deliveries/collections from depot can be organised via Royal mail website for a more appropriate date. Tracked Royal mail services for Controlled drugs allow the patient to have direct control over delivery day, offer a time range and delivery preference's while allowing the pharmacy team to ensure that GPS data, signature and image evidence is obtained upon delivery.

1.59 If the prescription is for a controlled drug, either the delivery driver is used (for "local deliveries") or a fully tracked service from Royal Mail known as RM tracked 24/48 service is used. For avoidance of doubt, where prescriptions are delivered by the local delivery driver (within a 30-mile radius of the Pharmacy), the delivery driver has a lockable safe in the boot of the car. The driver is instructed never to leave either the safe or the vehicle unlocked at any point during the delivery rounds. The CD deliveries are packaged separately to normal deliveries and marked clearly with CD stickers on the bag and flagged onto the pharmdel system as CD's, all failed deliveries are returned to the pharmacy and brought to the attention of the RP the same day. The driver is also required to sign the back of the CD prescriptions at the pharmacy before the delivery round and ask for ID from the patient or patients nominated representative at the door. Entries into the controlled drugs register on pharmsmart are made when the medication leaves the premises and the driver/courier are entered as the person collecting/delivering. Prescriptions are retained till positive confirmation of delivery for both local/courier deliveries. The Royal mail tracked service offers the patients the ability to track their package via email or text, gives them a delivery time range and allows them to choose the day of delivery. GPS, image and signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery. If the patient misses the delivery, Royal Mail provide a "failed delivery card". A redelivery can then be arranged with Royal Mail online, or patients can contact the pharmacy for advice.

1.60 All cold chain deliveries are carried out in accordance with verified and approved cold chain procedures. This ensures 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 service.

1.61 Non-local cold chain delivery is handled currently by a dedicated cold chain courier, Igloo, who have verified and approved cold chain procedures and meet the relevant criteria to ensure a fully monitored and dedicated cold chain service.

1.62 We aim to review our cold chain courier selection periodically; our current cold chain courier is IGLOO. A technical agreement between Igloo thermo logistics and Healthcare Time LTD is currently in place.

1.63 They are MHRA-approved, meaning they meet all the regulatory standards and are therefore able to offer a quality courier service to the pharmaceutical and life science sectors. IGLOO use high specification monitored refrigerated vehicles and have refrigerated storage facilities. They offer an end to end dedicated, temperature controlled and fully monitored cold chain courier service. All breaches of cold chain sent in this manner are notified to the driver/relevant person and any affected deliveries cancelled and pharmacy informed of the cold chain breach.

1.64 The patient is contacted once their prescription arrives to ascertain their availability to accept delivery of the cold chain medication. It is re-iterated to the patient that they must be available to accept and sign for the parcel due to its nature or make arrangements to have it delivered to an alternative address such as their office or work place if appropriate. The patient is informed that if they miss the delivery, they must organise a re-delivery.

1.65 They are also told that they will be updated as to the tracking data of their parcel via email notification.

1.66 The team ensures that any cold chain item prepared for delivery via the courier is kept in the ‘awaiting delivery’ section of the fridge, any accompanying items are marked with a fridge line sticker and information sticker that the cold chain item will be delivered separately via cold chain courier.

1.67 Once the patient has agreed and is fully made aware of the date the package will be delivered, the IGLOO cold call delivery is initiated via email ordering and relevant temperature range of 2 to 8 degrees Celsius, with required delivery date, address and weight is input. The item is packaged in a reinforced cardboard box with Styrofoam to protect it during transit and the box then remains in the ‘awaiting delivery section’ of the pharmacy fridge till the courier arrives to collect and upon hand over it is reconfirmed that the temperature range of 2 to 8 degrees will be maintained end to end. The item is then collected, the patient receives all of the tracking data and updates. Staff then monitor the tracking and delivery status of the package the next day till positive confirmation by way of electronic proof of delivery including signature is confirmed. Full temperature logs end to end are kept by the courier for each delivery.

1.68 If a delivery is unsuccessful the pharmacy is informed and the courier leaves a failed delivery card stating details of the failed delivery such as date, time and contact details for re delivery requests. The item is taken back to the courier’s warehouse for storage before re-delivery, cold chain is maintained throughout. In conjunction with the courier, we have a 72-hour maximum window for cold chain deliveries, the cold chain is kept intact until successful delivery to the patient. If 72 hours have passed without successful delivery to the patient, the courier returns the items to the pharmacy instead, while maintaining cold chain. Pharmacy will immediately get in touch with the patient and organise a re-delivery using the same dedicated courier service for a more convenient date.

1.69 All breaches of integrity of cold chain are monitored and detected via the processes put in place by us and the dedicated cold chain courier at every stage of the process. These systems also make the driver aware if there have been any breaches automatically. If such an event takes place, the driver will leave a failed delivery card at the patients address citing breach of cold chain as the reason and the pharmacy will also be notified. The stock with breached integrity will be returned to the pharmacy and will be segregated from the pharmacy stock to avoid the risk of being used again. Pharmacy will immediately get in touch with the patient and organise a re-delivery with new stock using the dedicated courier service.

1.70 The process places emphasis on preparation, ability to communicate with the patient prior to delivery, valuing the patient's delivery preferences, end to end cold chain monitoring and efficient delivery to ensure cold chain is maintained. We are also fully prepared to deal with any breaches to ensure patient safety.

Repeat Dispensing:

1.71 Repeat dispensing is provided according to the NHS Terms of Service.

1.72 Appropriate patients (with long term, stable medical condition/conditions) are identified (with regard to the Terms of Service) and advice is given about the benefits of this service via telephone, email, website or via the appropriate leaflets. Patients are reminded that they should only request items which they actually need.

1.73 Any dispensing of repeat NHS prescriptions and dosette dispensing as may be required under the Equality Act, is done via consultation of patients, prescribers and carers via telephone or other non-face to face contacts. These are requirements in addition to requirements for dispensing and assessing the patients' need for repeat supply. Issues identified of a clinical nature are addressed with the prescriber.

1.74 Medication on each occasion is only supplied where the pharmacist is content via a non-face to face consultation with the patient that the patient is taking and will continue taking the medication appropriately, is not getting any side effects and there have been no changes to their medicine regime or their health. If side effects or any reason is identified that the service might no longer be appropriate for the patient, the pharmacist immediately raises this with the prescriber through channels like a referral form, email or phone to allow a holistic review to take place of the patient's treatment and clarity around appropriateness of further supplies is sought. If changes are made by the prescriber such as a change of dose, quantity or stopping a medication, this is communicated to the patient via email/phone and information recorded into their PMR and repeat dispensing record.

1.75 All interventions, consultations, records and information of supply are recorded into the patients PMR and repeat dispensing record for future reference.

Disposal of Unwanted Medicines:

1.76 The disposal of unwanted medicine service is advertised on the pharmacy website and on the practice leaflet. Patients or their representatives cannot return any medicines directly to the pharmacy and the team follows our procedures to ensure safety and avoid any face-to-face contact.

1.77 To arrange the return of unwanted medicines to the Pharmacy the patient telephones and speaks to a member of the dispensary team. For controlled drugs this is always the pharmacist on duty.

1.78 Unwanted medicines from patients, children's homes and residential care homes are collected by the designated driver if local or via a tracked return service from Royal mail via pre-paid packaging. Returns are then segregated and stored accordingly in containers provided by the approved waste disposal contractor, contracted by the local

NHS England Team. The waste contractor (PHS) collects the unwanted medicines as per their procedure.

1.79 Return and destruction of Controlled drugs are carried out in accordance to the GPhC guidelines. Where waste is a controlled drug, this requires a Royal Mail pre-paid tracked signed for return service. The controlled items returned by the patient are then segregated from the rest of the controlled drugs, labelled "patient returned" and stored in the controlled drug cabinet until destroyed by an authorised witness and the responsible pharmacist. All CD returns are signed for, recorded on the CD destruction register, labelled as CD returns, segregated and stored correctly in accordance with legislation to await destruction.

1.80 Where the patient needs to return any sharps or clinical/contaminated waste they are informed of the local procedures for disposing of them. The pharmacy staff sign-post the patient to the relevant services.

1.81 Staff are informed of the risks of handling waste drugs and the correct procedure for handling those drugs and are provided with suitable protective equipment and materials to deal with spillages.

Signposting:

1.82 Further help or advice beyond the pharmacy input is provided on the pharmacy website. This includes details of local and national health and social care organisations and any NHS England recommended groups to provide support to patients. Information is also provided via email and telephone.

1.83 Patients are signposted to other health and social care professionals where this is appropriate via telephone, email, letter and written literature, and information on the pharmacy website. The pharmacy's website will contain links to other health care providers and also an A-to-Z healthcare section.

1.84 Staff are trained to use the WWHAM questions effectively and the RP takes a full medical history of the patient through the means of telephone, web chat and email consultation. Those patients, who require further support which cannot be provided by the pharmacy, are appropriately referred using reliable resources such as NHS Direct or NHS Choices.

1.85 We do not provide an appliance service and follow the terms of service in regards to referral/signposting of such patients.

1.86 Appropriate records are kept, including of any information given or referral made.

Promotion of Healthy Lifestyles (Public Health) and prescription linked intervention:

1.87 The provision of opportunistic healthy lifestyle advice is provided via telephone, writing/email or via the pharmacy website. There is pro-active participation and contribution to agreed national and local health campaigns. Leaflets and/or information packs are sent via the dispensed medicines bags or delivered per patient request. Social media campaigns on the pharmacy social media channels are also shared. Records are made of participating in health campaigns as required.

1.88 The pharmacy also pro-actively targets relevant patient groups, as appropriate, with healthcare advice through prescription linked interventions where a patient presents a prescription and it appears that the patient has diabetes, is at risk of coronary heart disease (especially those with high blood pressure), or smokes or is overweight. Records of interventions are made as required. Identification of patients takes place through three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process. This is through the use of lifestyle questionnaires available via email or sent to the patient and returned by post, during interactions e.g., remote advice

consultation or the repeat dispensing process which will indicate what conditions a patient suffers from. Advice is backed up with written material (sent by email or post or with the patient's medication) or by referring the patient to other sources of information or advice as appropriate.

1.89 All lifestyle interventions are recorded on the patient's PMR including the information provided by the patient and the information given to the patient, as well as any written materials that have been provided. All lifestyle interactions, advice (and requests for advice) operate without face-to face interaction (e.g., telephone, email, Skype, WhatsApp and via the website). Advice and help is 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.

1.90 Furthermore, there is regular staff training to enable all staff to give advice on healthy lifestyle campaigns using remote communication methods.

Discharge medicine Service:

1.91 The DMS procedure covers all the stages and regulations in detail. Referrals are made to the pharmacy via secure electronic message via pharm outcomes. A notification email is sent to the pharmacy email address which is accessible by staff and is checked at least 3 times a day. Referrals are actioned within 72 hours of receipt. Consent is taken by the referring trust and patients can withdraw consent in any stage.

1.92 Stage1 - Receipt of discharge referral

1.93 Patient details are checked, medicines on discharge are compared with admission via PMR and SCR. Any concerns are raised with the NHS trust and patient GP, notes are added to the PMR. Alerts are set to conduct stage 2 & 3 when the first prescription or contact is received. Any previous prescriptions are returned to spine if not appropriate for supply.

1.94 Stage2 - Receipt of first prescription following discharge

1.95 Pharmacist compared the discharge referral with the post discharge prescription to ensure no discrepancy. If one is found a referral is made to the GP to resolve any issue and records are made on the PMR. If consent is revoked in either stage 2/3/ prescriptions are not received or no contact is made with the patient after a reasonable number of attempts, concerns are relayed to the GP.

1.96 Stage3 - Shared decision-making discussion with patient

1.97 Patient knowledge of what medication they are taking and how they are supposed to be taking is checked, any gaps in knowledge are filled with advice. The conversation is confidential and provided via phone/video consultation. The patients PMR is updated and with the patients consent any information of value is shared with the GP/PCN to support the patients on going care. Patient is also offered the return service for any unwanted medicines and also the NMS service if relevant.

1.98 The procedure also deals with issues such as patients moving community pharmacies after stage 1, temporary closures and record keeping and payment. At the end of each month, for each DMS provision a report of standard dataset is submitted via MYS for payment.

Support for Self-Care:

1.99 Patients are provided with advice and support to help them look after their own health, especially on managing minor ailments, common conditions and long-term conditions. Appropriate advice on OTC medicine usage is provided via the website. Telephone,

email and video call consultation is also available. Appropriate records are kept as required.

Health campaigns

1.100 We participate in health campaigns as requested by the NHSCB, including through information provided on leaflets with prescriptions, the website and information is given to patients both opportunistically (where contact is made with patients through email, phone or WhatsApp, all contact is non-face to face) and in response to the dispensing service to ensure they are kept up to date in regards to [sic] the campaigns.

1.101 Patients are also evaluated for participation in a minimum of at least one clinical audit and whichever of the following as per NHCB specifications. Clinical audit is executed in compliance with NHCB's arrangements of receiving and processing data from the audit. Policy audit (to help development of the commissioning policies) is executed in compliance with NHCB's arrangements of receiving and processing data from the audit.

1.102 Appropriate records are kept as directed by NHSCB and in accordance with the Terms of Service.

Clinical Governance:

1.103 CG requirements cover a range of quality related issues, which are complied with.

1.104 This includes, clinical audits, compliance with Standard Operating Procedures, near miss records, patient safety incidents and drug recalls.

1.105 Patients are able to provide feedback for the services via an online or paper questionnaire survey (sent via the driver and post).

1.106 Practice leaflets are also available on the website which contain information approved by the Department of Health and provide information of the details required. Nothing in the pharmacy's practice leaflet or other material published by the pharmacy represents (either expressly or impliedly) that essential services are only available in particular areas of England or that the pharmacy is likely to refuse to provide prescribed medication by reference to particular categories of patients.

Information Governance:

1.107 All patient data is kept private and confidential in accordance with the NHS obligations including GDPR.

Complaints Procedure:

1.108 A complaints procedure is available in accordance with the GPhC and NHS requirements.

1.109 The procedure is available on the pharmacy website or can be emailed or delivered via the driver or post.

Compliance with GPhC guidance

1.110 In addition to the above the pharmacy complies with the March 2022 GPhC guidelines for distance selling pharmacies. This includes regular risk assessments and audits to ensure that the pharmacy continues to provide services safely and effectively and in accordance with current legislation, professional standards and guidance. A reactive review will occur if an audit identifies an issue or there are changes to law affecting pharmacy practice, a major change occurs, data breach has occurred, updates to

technology, negative feedback is received or If there are any safety concerns about an activity identified via reviews of safety/error logs.

1.111 There is a robust accountability trail on all levels of pharmacy service provision.

1.112 A Responsible Pharmacist is onsite at all times and is accountable for the services provided. There are also clear lines of accountability for pharmacy staff members including the designated delivery driver, making sure the medicines are made up correctly and delivered to the correct patient.

1.113 Courier companies such as Royal Mail and Igloo have been checked properly to make sure they are able to provide a safe and an efficient service.

1.114 All this is already detailed in the Standard Operating Procedures.

1.115 For the pharmacy to provide a safe and efficient service, records are kept where appropriate using main stream safe, secure and approved service providers such as Pharm smart. The pharmacy IT equipment is used to keep record of issues such as selling of P medicines via delivery, risk assessments and reviews, staff accountability and training, patient consent, complaints and patient intervention. Records are kept as per NHS guidelines and legislations.

1.116 All staff are properly trained and competent to provide safe and efficient services. Apart from the relevant pharmacy training courses, training is provided about data protection, communication skills where non face to face contact is involved and on specialised equipment and technology. Staff are also trained on the Identity Verification and Authentication Standard for Digital Health and Care Services, to allow them to check that the patients receiving pharmacy services are who they claim to be.

1.117 The pharmacy premises are fit for the purpose of providing safe and efficient pharmacy services and meet the standards required by the GPhC.

1.118 The information provided about both the current premises and proposed premises and the services provided from them are honest and not misleading to the public. As with our current premises the proposed premises are also closed to the public with controlled access via doors, locks and CCTV to prevent anyone unauthorised from entering.

1.119 Pharmacy services are provided via a website and application that is associated with the registered pharmacy. The information is clear, concise and provide all the relevant details required by the GPhC including the GPhC number, pharmacy details and registration status. All information is updated regularly as and when required. For further details please refer to the detailed section on the website earlier in this document.

1.120 Due to the risks associated with supplying medicines in the distance selling context, the pharmacy regularly assesses the suitability and timescale of the method of supply, dispatch and deliver of medicines, including controlled drugs and fridge items. Appropriate Courier services such as Igloo cold-chain and Royal mail tracked services, which can accommodate all requirements are used to deliver medication throughout England. Risk assessments are used to identify and manage all potential problems.

1.121 Due to the nature of non-face to face contact, all staff are provided training to make sure they can communicate any vital information clearly and effectively.

1.122 Patients are given clear and concise information regarding the choice available to them in using whichever pharmacy they want to provide a service for them. Informed consent is gained in order for this pharmacy to provide the services to them via the website and pharmacy leaflets. A record is kept of all consents received.

1.123 The equipment and facilities used are designed for the intended purpose of pharmacy service provision. Website and electronic communication are secure, maintained and serviced regularly. Maintenance logs are kept at all times. The pharmacy also complies with the necessary information provided by the NHS Data Security and Protection Toolkit."

2 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 22 January 2024 states:

2.1 "West Yorkshire ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning."

Extract from the Pharmaceutical Services Regulations Committee (PSRC) report:

2.2 "The Pharmaceutical Services Regulations Committee (PSRC) granted the application based on the following regulations and considerations.

2.3 This application was considered under Regulation 24(1) (a) (b) (c) (d) & (e), Regulation 24(2), Regulation 24(3a,b & c), Regulation 36, 37 and 65 for the No Significant Change Relocation and 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. It [sic]

2.4 Regulation 31 The Committee noted that Regulation 31 does not apply as there are no other pharmacies at the same or adjacent premises.

2.5 Regulation 24(1)(a) is met as the applicant identified that their patients falls into one patient group 'patients who access services other than at the premises' as none of the patients are accustomed to accessing pharmaceutical services by attending the premises, therefore, no patients would find the pharmacy significantly less accessible.

2.6 Regulation 24(1)(b) is satisfied. The applicant has confirmed that they will provide the same opening hours and services at the proposed new premises as are provided at the existing premises and has confirmed that there will be no interruption to service provision.

2.7 Regulation 24(1)(c) is satisfied. Granting the application would not cause a significant detriment to the proper planning of services.

2.8 Regulations 24(1)(d&e) are met as the same services will be provided and there will be no interruption to services during the relocation.

2.9 Regulations 24(2) is not applicable. The pharmacy is not proposing to relocate outside the area of the HWB.

2.10 Regulations 24(3a&b) are not applicable. The individual criteria do not apply to this pharmacy as the applicant does not intend to relocate outside a retail area or outside a primary care centre.

2.11 Regulations 24(3c) is not applicable to the application as the pharmacy has not relocated in the last 12 months.

2.12 Regulations 36 and 37 are not applicable as the premises are not within a controlled locality or within 1.6 km of one.

2.13 Regulation 65 is not applicable as NHS England will not be directing the pharmacy's opening hours.

2.14 Regulation 66 is not applicable as NHS England does not intend to direct further services to be provided.

2.15 This application was also 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.

2.16 Regulation 31. The Committee noted that Regulation 31 does not apply, as there is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this application and the proposed premises are located in a business centre.

2.17 Regulation 25(2)(a) is met as no primary care provider with a patient list is present within the same premises as the proposed site.

2.18 Regulation 25(2)(b) is met as the applicant demonstrated how services will be provided remotely, and without interruption throughout the given opening hours.

2.19 Regulation 64 (detailed below) are met based on that fact that the applicant has provided assurance in the additional information that the specific conditions set out in Regulation 64 are met.

Distance selling premises: specific conditions of approval

2.20 As the application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Bradford Health and Wellbeing board in respect of the premises included in the application that inclusion will be subject to the following conditions:

2.20.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;

2.20.2 the means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;

2.20.3 the proposed 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;

2.20.4 the pharmacy procedures for the premises must be such as to secure:

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

2.20.4.2 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; and

2.20.5 nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:

2.20.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or

2.20.5.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the applicant is limited to other categories of patients)."

2.21 The Committee noted and considered that this was the second application for a NSCR application by this applicant. NHS Resolution had highlighted some concerns during the appeal from the previous application and the committee felt that these had been addressed in the second applications and all necessary points had been covered.

2.22 The committee agreed that it was a robust application, although they had one concern over the fact that Royal Mail would not leave a parcel unless a patient had confirmed a safe place or requested to leave a parcel with a neighbour. However, couriers are widely known to leave packages for customers in places unbeknown to them for quickness of delivery. It was agreed that although this could present a slight issue if protocol was not followed, this issue is not under the control of the contractor but rather the courier.

2.23 Decision: PSRC granted the application for a relocation to a neighbouring HWB area that does not result in a significant change on the grounds that the applicant has met the requirements set out in Regulation 25 and 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.24 Appeal rights are granted to:

2.24.1 Crossflatts Pharmacy."

3 The Appeal

In a letter dated 29 January 2024 addressed to NHS Resolution, Rushport Advisory LLP on behalf of Crossflatts Pharmacy ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for S&A Health Limited t/a Crossflatts Pharmacy, in the above application and have been instructed by my client to submit the following appeal to the decision of the ICB to approve the above application. A copy of the decision letter is enclosed with this letter.

Grounds of Appeal

3.2 The application falls to be considered under regulation 24 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. In addition, as this application relates to a pharmacy which has been approved as a distance selling pharmacy, NHS England is also required to assess the application against the requirements of regulation 64(3).

3.3 It is for the Applicant to satisfy the Committee that all the regulatory requirements have or will be met and the application must be refused unless the Committee is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure –

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

3.3.2 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.

3.4 In addition, distance selling pharmacy premises are subject to the requirements specified under Regulation 64(3) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

3.5 In relation to regulation 24, we note that the Applicant states that they provide NMS as an Advanced Service, but provides no details about patients who receive the service as a "patient group" and there is no way of knowing whether the relocation would make the pharmacy significantly less accessible for this group.

3.6 Whilst the Applicant has provided some commentary on their processes and procedures, they are silent on a significant number of parts of the relevant legal test. The Applicant confirms that "all of the current provisions, policies and procedures including SOPs will remain in place after the move and indefinitely" – however, these SOPs have not been provided and the Applicant's previous application was refused at appeal (SHA/25839) when we also presume these SOPs were in place and similarly not provided.

3.7 In relation to providing services which are safe and effective, the Applicant has likewise provided insufficient detail to enable the Committee to be satisfied that all essential service provision would be both safe and effective.

3.8 The Applicant refers states that "Deliveries comply with the GPhC guidelines of medicines delivery". It is unclear what the Applicant is referring to and we invite the Applicant to provide a copy of these guidelines that are supposedly issued by the GPhC. We are unaware of any GPhC guidance that suggests that a "portable medical fridge" in a van is a suitable way to deliver cold chain items and we ask that the Applicant provides details of what model of portable fridge they use and the software for monitoring temperatures, or at least provide sufficient detail to enable the Committee to confirm that this fridge and software exist. It must be remembered that this application is for a relocation of existing premises and the Applicant has stated that the same procedures will remain in place. It should therefore be simple for the Applicant to provide evidence to support their claims.

3.9 We note that the Applicant permits medicines to be left in what they describe as a "safe place". We submit that this is unlikely to be appropriate for medicines or be considered "safe and effective". The Applicant does not provide detail of what place would be considered a "safe place" and it must be remembered that a location that a patient may consider to be safe may not be appropriate for the delivery of medicines.

3.10 With respect to exemptions the Committee will note that the Applicant provides very little detail about how this process will be carried out and appears to be unaware of the requirements of their Terms of Service. As an example, the Applicant proposes that patients will be able to provide a photocopy of an exemption card, or staff will simply phone patients to ask what type of exemption they have.

3.11 Finally and whilst not a matter that the Committee will likely give consideration to, the Applicant should note that the GPhC professional standards do not permit a pharmacy to claim that they are better than other pharmacies and their website should not contain the sentences "Leave the rest to us the Number 1 best online pharmacy in the UK", or "The Best Online Pharmacy UK Has to offer."

3.12 In this case, we submit that NHS England cannot be satisfied that the test under regulation 64(3) is met and the application must therefore be refused.

3.13 We look forward to hearing from you in due course."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 “Thank you for allowing West Yorkshire ICB the opportunity to provide representation in relation to the above appeal, we would like to take this opportunity to make comment on the information provided by the appellant as part of the appeal.

4.1.2 West Yorkshire ICB approved this second application by this contractor for a No Significant Change Relocation (NSCR) to a Neighbouring HWB area that does not result in a significant change from 27 Newmarket St, Skipton BD23 2JE to Unit 6, Crown Works, Bradford Rd, Sandbeds, Keighley, BD20 5LN on the grounds that the applicant had demonstrated that they would comply with Regulation 24, Regulation 31 and Regulation 64 - which sets out the specific conditions to be met by applications for Distance Selling Premises of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.3 As per the minutes of the PSRC held 29 November 2023, the committee recognised that this was the second application for this NSCR and considered that the NHS Resolution appeal highlighted some concerns from the previous application. The committee felt that these had been addressed in the second application and all necessary points covered.

4.1.4 West Yorkshire ICB have nothing further add, the application was approved on the grounds that the applicant had demonstrated in the application and additional information provided, that they would comply with 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 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.5 Based on the original application and information provided at the time West Yorkshire 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 TEMPLE BRIGHT ON BEHALF OF THE APPLICANT

4.2.1 “I act for Healthcare Time Limited. On behalf of my client I write further to your letter of 5th February 2024 and in order to respond to an appeal by S&A Health Limited against a decision of NHS England to grant the above application.

4.2.2 As NHS Resolution will be aware, there is a significant background to my client’s relocation application.

4.2.3 My client first applied to relocate its pharmacy to the same site as that proposed in the current application in July 2022. In support of its application, my client provided information to explain how all essential services were being (and would be from the proposed site) provided safely and effectively in the distance selling context.

4.2.4 My client’s application was granted by NHS England by a decision dated 20th December 2022.

4.2.5 However, that grant was subject to an appeal by S&A Health Limited on 15th January 2023. My client responded, in detail, to the matters raised by the appellant.

4.2.6 Notwithstanding the information provided by my client to NHS Resolution (and without NHS Resolution indicating that it had concerns regarding what it

considered to be some insufficient information), NHS Resolution refused my client's application (appeal reference SHA/24830).

4.2.7 NHS Resolution's decision to refuse my client's application was based on narrow grounds, namely:

4.2.7.1 The integrity of cold chain deliveries

4.2.7.2 The packaging to be used by my client to send medication to patients

4.2.7.3 How my client would assess whether it was required to refuse to provide drugs or appliances ordered on a repeatable prescription

4.2.7.4 Whether my client's website had a "health promotion zone"

4.2.8 The appeal decision was made against the backdrop of a pharmacy which had been providing pharmaceutical services for many years without any complaint from patients or NHS England.

4.2.9 NHS England had granted my client's application, concluding that it, itself, was satisfied that my client's pharmacy was complying, and would comply from the proposed location, with its obligations under the NHS Terms of Service. Against that background, it was somewhat surprising that NHS Resolution refused my client's application on appeal, particularly without giving my client the opportunity to comment, specifically, upon the above 4 concerns.

4.2.10 In light of the refusal decision, my client reapplied to NHS England for a no significant change relocation. My client's new application specifically addressed the 4 concerns which were identified by NHS Resolution in its appeal determination. My client's new application was submitted in June 2023.

4.2.11 Once again, S&A Health Limited submitted representations to NHS England on my client's application, and these representations were addressed, in full and in detail, in my letter of 18th October 2023.

4.2.12 My client's application was again granted by NHS England by a decision dated 22nd January 2024, with NHS England concluding that, in its opinion, the application met the requirements of regulation 25(2)(a) and 25(2)(b). In particular, NHS England noted as follows:

"The Committee noted and considered that this was the second application for a NSCR application by this applicant. NHS Resolution had highlighted some concerns during the appeal from the previous application and the committee felt that these had been addressed in the second applications and all necessary points had been covered."

4.2.13 NHS England's decision to grant my client's application has, again, been appealed by S&A Health Limited by an appeal letter dated 29th January 2024. In relation to the matters contained within that letter of appeal, my client comments as follows:

New Medicines Service

4.2.14 This service is provided remotely from the premises to all patients who are eligible. Since patients who receive this service do so remotely, they do not form part of a "patient group" which is accustomed to accessing the service at the listed premises. Patients who receive the NMS service from the pharmacy would therefore be entirely unaffected by the proposed relocation.

4.2.15 This is a matter that was noted and accepted by NHS Resolution in its previous appeal decision (paragraphs 6.9 to 6.12).

Processes and procedures

4.2.16 The appellant states:

"Whilst the Applicant has provided some commentary on their processes and procedures, they are silent on a significant number of parts of the relevant legal test. The Applicant confirms that "all of the current provisions, policies and procedures including SOPs will remain in place after the move and indefinitely" – however, these SOPs have not been provided and the Applicant's previous application was refused at appeal (SHA/25839) when we also presume these SOPs were in place and similarly not provided.

In relation to providing services which are safe and effective, the Applicant has likewise provided insufficient detail to enable the Committee to be satisfied that all essential service provision would be both safe and effective."

4.2.17 The appellant made exactly the same comment in support of its previous appeal. However, NHS Resolution was satisfied with all of the information that had been provided by my client in support of its previous application save for the 4 matters summarised above. The information provided by my client in support of its current application addresses those additional 4 matters.

4.2.18 If NHS Resolution considers that there remains any area of concern in relation to the information provided by my client then NHS Resolution is kindly requested to identify those areas in order to give my client the opportunity to address those specific concerns before this appeal is determined. As NHS Resolution will appreciate, it is costly and time-consuming to have to re-apply to NHS England pursuant to a refusal and would be a much more effective use of resources (both my client's resources and those of the NHS) if any issues can be resolved fully and finally in relation to the current appeal.

GPhC guidance on delivery

4.2.19 It is surprising that Rushport Advisory LLP states that they are "unaware of any GPhC guidance" in relation to medicine delivery. The GPhC has provided guidance on providing services at a distance which makes several references to deliveries, including in relation to temperature-controlled deliveries.

4.2.20 My client has never claimed that GPhC guidance makes explicit reference to specific methods of delivery, but my client's methods of delivering medicines to patients (as summarised in its application form and subsequent correspondence to NHS England) complies with the GPhC's guidance.

4.2.21 The appellant suggests that my client should provide "details of what model of portable fridge they use and the software for monitoring temperatures", but there is no proper basis upon which this information is sought: NHS Resolution would not be assisted in any way by knowing "what model of portable fridge" my client uses and the "software" used for monitoring temperature. However, my client has, of course, provided information and photographs in its letter to NHS England of 18th October 2023 which, I assume, NHS Resolution has obtained but a copy of which can be provided if required, of the fridge and the monitoring system, including example printouts of how the temperature is monitored. I am also attaching, to this letter, a further screenshot which shows the amount of information that is logged by the thermadata system, including temperature, log duration, sample interval rate, number of samples, max/min values and an alarm summary.

4.2.22 In relation to national deliveries, as stated in my client's supporting information, my client now uses Igloo for cold chain deliveries. Igloo provide a specialist cold-chain supply service which monitors temperatures in real time. My client can request temperature logs for a specific delivery from them if needed.

4.2.23 It is submitted that the information provided by my client is sufficient to satisfy NHS Resolution of the relevant regulatory test. However, once again, if NHS Resolution considers that it requires additional information about these matters in order to determine this appeal then NHS Resolution is urged to request this information explicitly from my client before it determines this appeal.

4.2.24 NHS Resolution will be aware that its concern in relation to cold chain supply related only to how my client would be able to monitor the temperature of cold chain products in real time. My client has addressed those concerns in its current application, including supplying evidence of how real time temperature monitoring works in practice.

Leaving medicines in a "safe place"

4.2.25 The appellant raised an identical comment in its last appeal, which was dismissed by NHS Resolution (see paragraph 6.53 of the previous appeal decision). For the avoidance of doubt, my client's application states under the website section that it has a 'Sign up page with information, confirmation and consents for delivery including use of safe places and their exclusions: https://timepharmacy.co.uk/sign-up/'. By clicking on delivery information (https://timepharmacy.co.uk/delivery-information/) visible on the sign up page, patients can gain comprehensive information on what is acceptable as a safe place and how my client communicates their preference to its delivery partners.

Prescription charge exemptions

4.2.26 In its letter of appeal, the appellant states as follows:

"With respect to exemptions the Committee will note that the Applicant provides very little detail about how this process will be carried out and appears to be unaware of the requirements of their Terms of Service. As an example, the Applicant proposes that patients will be able to provide a photocopy of an exemption card, or staff will simply phone patients to ask what type of exemption they have."

4.2.27 It is not at all clear what point the appellant is seeking to make here, or what criticism is being made of my client's procedures.

4.2.28 For the avoidance of doubt, the Terms of Service require an NHS Pharmacist to ask the person who makes a declaration that they are exempt from the prescription charge to produce satisfactory evidence of such exemption (unless certain entitlements to exemption apply, or unless a real time exemption check can be made with NHSBSA through the pharmacy's PMR system). My client has provided information to confirm how this information is requested and how the suitable evidence may be provided. Prescriptions are appropriately endorsed.

4.2.29 Where no satisfactory evidence is provided, my client informs patients who have declared an exemption that checks are routinely carried out to ascertain entitlement to exemption and to detect fraud or error.

Comparative marketing

4.2.30 As the appellant readily acknowledges, the use of comparative marketing on my client's website is not a matter which engages regulation 25 (and,

consequently, is irrelevant to the determination of this application). For the avoidance of doubt, my client has checked with the GPhC which has confirmed that the guidance to which the appellant refers in its letter of appeal does not exist, but out of an abundance of caution has amended its website.

Conclusion

4.2.31 In conclusion, for the reasons given above, my client invites NHS Resolution to dismiss this appeal and to grant my client's application."

4.3 COMMUNITY PHARMACY WEST YORKSHIRE

4.3.1 "Thank you for your letter dated 5th February 2024 concerning the above application.

4.3.2 Community Pharmacy West Yorkshire members still feel that their comments made in their letter to [SS] on 16th September 2023 are valid. These were as follows.

4.3.3 Community Pharmacy West Yorkshire members would like to make the following observations:

4.3.3.1 Paragraph 1 of Schedule 2 has been met

4.3.3.2 This application does not appear to breach regulation 31

4.3.4 And the following comments:

4.3.4.1 With regards (sic) Regulation 24 Members did not believe that this relocation would significantly alter the accessibility of pharmaceutical services.

4.3.4.2 Members felt that it was unlikely that granting this application would cause significant changes to the arrangements that are in place for the provision of pharmaceutical services or significant detriment to the proper planning of the provision of pharmaceutical services.

4.3.4.3 The proposed services appear to be the same as those provided at the current premises.

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

5 **Observations on representations**

5.1 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPELLANT

5.1.1 "I act for S&A Health Limited t/a Crossflatts Pharmacy, in the above application and have been instructed by my client to submit the following final comments to address the points raised by Healthcare Time Limited in its reply to this appeal.

5.1.2 The Applicant acknowledges that its previous application for relocation was refused and this is correct. It is clear that the Applicant has attempted to address some of the failings in its operating procedures since the previous refusal and has made changes to how it operates. This is clearly an acknowledgment that despite the Applicant stating that they had been "*providing pharmaceutical services for many years without any complaint from*

patients or NHS England", their procedures were, nevertheless, defective in some areas.

5.1.3 It is important to therefore consider whether the deficiencies have been remedied and we say that they have not been for the following reasons.

GPhC Guidance on Delivery

5.1.4 In its initial supporting information the Applicant stated;

All dispensed items are delivered by Royal Mail, a courier service or by a designated staff member depending upon the nature of the item and the patient's address to ensure delivery to patients anywhere in England. Deliveries comply with the GPhC guidelines of medicines delivery. [my emphasis]

5.1.5 In our letter of appeal we pointed out that no such guidance existed. Whilst not directly relevant to the legal test, this simply showed that Applicant was not in fact aware of what they were doing or what guidance existed.

5.1.6 In its response to my client's appeal, the Applicant now claims that this reference to "GPhC guidance" was in relation to the GPhC's general guidance on the remote delivery of pharmacy services instead of accepting that that there are no such "guidelines of medicines delivery" and instead the GPhC provides a list of bullet points that a pharmacy is required to "make sure" it does, rather than provide any guidance. This simply points to the Applicant being unaware of what standards to follow.

Local Fridge Line Deliveries

5.1.7 We note that the Applicant's representative claims that there is "no proper basis" for our request to know what type of "fridge in a van" it proposes to use and claims that *"NHS Resolution would not be assisted in any way by knowing "what model of portable fridge" my client uses and the "software" used for monitoring temperature*".

5.1.8 Respectfully, we disagree. In their application that was refused in 2023 the Applicant stated;

Local cold chain deliveries involve the delivery driver adding the cold chain item to a polystyrene cool box which contains a calibrated thermometer. Ice packs are then added with cardboard blockers to ensure the temperature of the products remains between 2 and 8 degrees while delivering locally.

5.1.9 It is clear that only last year, the Applicant had no idea what methods of delivery would be considered safe and effective.

5.1.10 Now we are told that the Applicant has changed their processes (and presumably already uses new processes given the previous refusal) and will now use a plug in fridge in a van, but they cannot tell the Committee anything about this fridge. The Applicant refers to a letter / pictures of 18 October 2023 that we do not have a copy of and has chosen not to resubmit this letter for whatever reason.

5.1.11 The Applicant does provide a screenshot relating to a product called "thermadata". However, this screenshot appears to be taken from the Thermadata website rather than reflecting what the Applicant actually does or what product they use. Given that this is a relocation application the Applicant should already be operating using this system and it should be easy for them to provide evidence in relation to it rather than claiming that evidence would

not be helpful. Many of these products cannot be used in fridges as they must be located outside of the fridge in order to be able to transmit data to the receiver. If the Applicant uses this system then they should have explained how it works.

5.1.12 The Applicant asks that NHS Resolution makes further requests for information if it is not satisfied with the evidence that that has been provided. However, the Applicant has had its chance to respond to specifically raised points and has failed to provide the evidence required and the application should be refused.

Safe Place and Marketing Claims

5.1.13 We note that the Applicant has made significant changes to its website with lots of new information about what may or may not be a safe place for leaving deliveries. The significant amount of new information provided does appear to correct previous mistakes. Similarly, we note that the Applicant's website no longer claims that their pharmacy is better than other pharmacies.

Prescription Change Exemptions

5.1.14 Whilst the Applicant may not understand the point that has been made in my client's appeal in relation to accepting photocopies of exemption cards as proof of exemption or simply phoning patients to ask what type of exemption they have, it is something that they should be aware of as it is the actual exemption certificate that must be shown (where one is being relied upon) and a photocopy should not be accepted as evidence.

5.1.15 In this case, we submit that NHS Resolution cannot be satisfied that the test under regulation 64(3) is met and the application must therefore be refused. The Applicant has shown that it is either unaware of or unable to explain how it currently operates the pharmacy or how it will provide safe and effective services in the future

5.1.16 We look forward to hearing from you in due course."

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

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

6.5 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) 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).

6.6 The Committee noted that the Applicant had not provided any information 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.

6.7 The Commissioner, in its decision letter, noted that Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site. The Committee noted that this had not been disputed either on appeal or in subsequent representations. The Committee therefore determined, on the basis of the information before it, that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 24(2)

6.8 The Committee noted the comments from the Commissioner in its decision letter that "*Regulations 24(2) is not applicable. The pharmacy is not proposing to relocate outside the area of the HWB*."

6.9 The Committee noted that the application form states that the Applicant's current premises is located in the North Yorkshire HWB area and that they are proposing to relocate to premises located within the neighbouring Bradford HWB area. The Committee noted the information contained in the application form and that this had not been disputed either on appeal or in subsequent representations by any party. Based on the information before it, the Committee was of the view that the application was for a no significant change relocation for inclusion in the pharmaceutical list of a neighbouring HWB and as such fell to be considered under the provisions of Regulation 24(2).

6.10 The Committee therefore considered the application in accordance with Regulation 24(2) which states:

(2) Section 129(a) of the 2006 Act does not apply to any application from a person already included in a pharmaceutical list for the area of a HWB (HWB2) for inclusion in the pharmaceutical list for the area of a neighbouring HWB (HWB3), or inclusion in the pharmaceutical list for the area of HWB3 also in respect of other premises than those already listed in relation to that person if -

(a) the purpose of the application is to relocate to different premises;

(b) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises (P1), the location of the new premises (P2) is not significantly less accessible;

(c) in the opinion of the NHSCB, 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 HWB3's, or

(ii) in a controlled locality of a neighbouring HWB (including HWB2), where that controlled locality is within 1.6 kilometres of P2;

(d) the NHSCB 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 HWB3;

(e) the services the applicant undertakes to provide at P2 are the same as the services the applicant has been providing at P1 (whether or not, in the case of enhanced services, the NHSCB chooses to commission them); and

(f) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow); and

(g) the applicant consents to –

(i) where the applicant has only one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of the applicant's name from that pharmaceutical list, or

(ii) where the applicant has more than one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of P1 from being listed in relation to the applicant in that pharmaceutical list,

with effect from the date on which the applicant undertakes to provide pharmaceutical services from P2.

Regulation 24(2)(a) & (b)

6.11 The Committee noted that the Applicant is applying to relocate to different premises.

6.12 The Committee noted that, in its decision letter the Commissioner states that the Applicant identified its patients as falling into "*one patient group 'patients who access services other than at the premises' as none of the patients are accustomed to accessing pharmaceutical services by attending the premises, therefore, no patients would find the pharmacy significantly less accessible*." The Committee noted that this had not been disputed on appeal or in subsequent representations.

6.13 The Committee noted that the Applicant provides the NMS service remotely. In its application form, the Applicant states that the current premises does not have room for a consultation room and that the NMS service is provided remotely via non face-to-face contact.

6.14 The Committee noted the comments from the Appellant that *"… there are no details of patients who receive this service…"* and goes on to state "…*no way of knowing if the relocation is significantly less accessible for these patients"*.

6.15 The Committee noted the information provided by the Applicant in their representations at 4.2.14 above which confirms that NMS is provided remotely. Based on the information before it, the Committee was of the view that no issue arose as the NMS service is being accessed remotely rather than at the existing premises.

6.16 The Committee was therefore of the view that the conditions in Regulation 24(2)(a) & (b) are met.

Regulation 24(2)(c)

6.17 The Committee noted that in its decision letter the Commissioner had considered Regulation 24(1)(b) stating that it "is satisfied" as "*the Applicant has confirmed that they will provide the same opening hours and services at the proposed new premises as are provided at the existing premises and has confirmed that there will be no interruption to service provision."* The Committee noted that this is not the correct provision which is set out in Regulation 24(2)(c).

6.18 On the information provided the Committee was of the opinion that the granting of 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 in any part of Bradford HBW's area or in a controlled locality of a neighbouring HWB (including North Yorkshire HWB's area), where that controlled locality is within 1.6 kilometres of the proposed premises. The Committee concluded that the condition in Regulation 24(2)(c) is met.

Regulation 24(2)(d)

6.19 The Commissioner considered Regulation 24(1)(c) stating that it "*is satisfied*" and going on to state "*Granting the application would not cause significant detriment to the proper planning of services."* which had not been disputed by any party either on appeal or in subsequent representations. The Committee considered that this information is similar to that need to be considered in Regulation 24(2)(d). 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 Braford HWB area and therefore concluded that the condition in Regulation 24(2)(d) is met.

Regulation 24(2)(e)

6.20 The Committee noted that the Applicant had given an undertaking, in their original application form, that the same services will be provided at the proposed site. On the information provided, the Committee determined that the condition in Regulation 24(2)(e) is met.

Regulation 24(2)(f)

6.21 In relation to condition 24(2)(f), the Committee noted the Applicant had confirmed in its application, that there will be no interruption to service provision by the relocation to the new premises. On the information provided the Committee therefore determined that the condition in Regulation 24(2)(f) is met.

Regulation 24(2)(g)

6.22 The Committee noted that section 10 of the application form demonstrates that the Applicant had consented to the removal of its current premises from NHS England's pharmaceutical list in respect of the North Yorkshire HWB and, should the application be approved, the inclusion of its proposed premises in NHS England's pharmaceutical list in respect of the Bradford HWB effective from the date on which the Applicant undertakes to provide pharmaceutical services from the new premises. The Committee noted that parties have not commented on Regulation 24(2)(g), therefore, based on the information provided, it determined that the condition in Regulation 24(2)(g) is met.

Regulation 24(3)(d)

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

6.24 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).

6.25 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.

6.26 In relation to Regulation 24(3)(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) 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 13 (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.

6.27 The Committee also had regard to the provisions of Schedule 2 to the Regulations show 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 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.

Regulation 25(1)

6.28 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)

6.29 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. The Commissioner, in its decision, determined that the application did not need to be refused on the basis on Regulation 25(2)(a) and this was not disputed by any party either on appeal or subsequent representations.

6.30 Based on the information available to it, the Committee therefore 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)

6.31 The Committee noted the comments in the Applicant's supporting information with their application form that "*the pharmacy is simply moving to a neighbouring HWB*" and "*the current provisions, policies and procedures satisfy all the regulations in relation to this application and will continue to do so after the move has been completed*." Further the Applicant states "*this should satisfy NHS England that the pharmacy is operating safely and effectively and is providing services in accordance with the Terms of Service*." Whilst the Committee acknowledged that the Applicant was currently offering services as a distance selling pharmacy, it was mindful of the Regulations and therefore proceeded to determine the application in accordance with Regulation 25(2)(b).

6.32 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 current procedures for the provision of essential services.

6.33 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.

6.34 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicate 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.

6.35 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, the evidence put forward has taken the form of the original application and the representations on the appeal which the Applicant has prepared.

6.36 The Committee noted in the application form it states:

6.36.1 "*There will be no interruption to the services which this pharmacy provides."*

6.37 The Committee noted that the application form goes on to state:

6.37.1 "*The pharmacy will continue to provide essential services to any person in England without face to face contact through the use of suppliers, couriers and service providers*

…"

"A Responsible Pharmacist is present and in charge during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients who live anywhere in England who require and request essential services. Where necessary locum cover is arranged through the Applicant's extensive network of pharmacist colleagues and through locum agencies. This ensures that the Pharmacy always has a responsible pharmacist signed in and present during its contracted hours. …"

6.38 The Applicant further states *"A Responsible Pharmacist is onsite at all times and is accountable for the services provided."*

6.39 The Committee noted that throughout the application form and supporting information the Applicant states that essential services will be provided without face to face contact between anyone receiving the services and the pharmacy staff.

6.40 The Committee noted that the Applicant "*… will provide the patient with appropriate advice (by telephone, email, live chat via WhatsApp and video calls) as required."* And further that "*contact with patients is made via email, telephone, live chat via WhatsApp, video calls, leaflets and notes."*

6.41 The Applicant goes on to state:

6.41.1 "*As with our current premises, the proposed premises are also closed to the public with controlled access via doors, locks and CCTV to prevent anyone unauthorised from entering."*

6.42 The Committee noted the references to the local delivery driver in the application from but also noted reference is made throughout to the provision of services to all of England and the use of Royal Mail and couriers, which "*have been checked properly to make sure they are able to provide a safe and an efficient service*".

6.43 The Committee was aware that after the pharmacy relocates, 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.

6.44 The Committee was satisfied that the provision of services would be without interruption, would be without face to face contact and would be available to persons anywhere in England. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

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

Dispensing of drugs and appliances

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

6.47 The Applicant stated:

6.47.1 "*Prescriptions are received at the pharmacy by post via the use of pre-paid envelopes and via ETP/EPS through patient nominations which are requested by the patients directly via the surgery, our website, Healthera app or telephone."*

6.48 And further:

6.48.1 *"All dispensed items are delivered by Royal Mail, a courier service or by a designated staff member depending upon the nature of the item and the patient's address to ensure delivery to patients anywhere in England. Deliveries comply with the GPhC guidelines of medicines delivery.*

…

In regards to [sic] choice of delivery method, for local deliveries (up to 30-mile radius, but may be extended at the discretion of the RP) the delivery driver can deliver the medication. ..

…

All non-local deliveries (except for cold chain products) are made by Royal Mail"

6.49 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

6.50 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.

6.51 The Committee noted the comments from the Applicant regarding "Emergency" supplies being carried out at the request of the prescriber. The Committee noted

reference to essential services being delivered by several methods of non-face to face communication including telephone and email and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

6.52 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

6.53 The Committee noted the comments from the Appellant with regard to exemptions and that the Appellant is of the view that the Applicant has provided very little detail about how this process will be carried out.

6.54 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.

6.55 The Committee noted in its application form, the Applicant states:

6.55.1 *"Exemptions from payments are clarified by:*

Phoning patients and asking about the type of exemption, the card exemption number and the date of expiry

Collecting their exemption type on the online nomination form they fill out

Additionally, seeking evidence of the exemption where appropriate to do so (such as a photocopy of the exemption card) and also.

Recording the exemption information given on the PMR system."

6.56 The Committee further noted the comments from the Applicant's representative in its representations which stated:

6.56.1 *"For the avoidance of doubt, the Terms of Service require an NHS Pharmacist to ask the person who makes a declaration that they are exempt from the prescription charge to produce satisfactory evidence of such exemption (unless certain entitlements to exemption apply, or unless a real time exemption check can be made with NHSBSA through the pharmacy's PMR system). My client has provided information to confirm how this information is requested and how the suitable evidence may be provided. Prescriptions are appropriately endorsed.*

Where no satisfactory evidence is provided, my client informs patients who have declared an exemption that checks are routinely carried out to ascertain entitlement to exemption and to detect fraud or error."

6.57 Based on the information before it the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

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

6.59 The Applicant stated "*Prescription charges are made via 2 secure methods which are invoice, bank transfer or by phone using a credit/debit card or for local deliveries via handheld mobile card machine."*

6.60 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

6.61 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 Relations 2001 and, in particular, Regulations 14 and 16, are met).

6.62 The Committee considered the information provided by the Applicant in their application form.

6.62.1 "All dispensed items are delivered by Royal Mail, a courier service or by a designated staff member depending upon the nature of the item and the patient's address to ensure delivery to patients anywhere in England. Deliveries comply with the GPhC guidelines of medicines delivery.

In regards to [sic] choice of delivery method, for local deliveries (up to 30-mile radius, but may be extended at the discretion of the RP) the delivery driver can deliver the medication. For local deliveries the delivery driver texts/emails the patients a definitive time period e.g., afternoon and date of delivery. The driver has access to the patient's delivery preferences as they are listed on the delivery label/pharmdel app. If a patient has a safe place or request to leave with a neighbour set as a confirmed and consented delivery preference prior to any delivery leaving the premises, we try our utmost to honour these preferences but make the patient fully aware that it may not be possible in certain circumstances such as delivery of controlled/fridge drugs. All deliveries are subjected to a robust audit system.

Local deliveries made by the delivery driver are tracked via a cloud/app based software system called Pharmdel. All local deliveries are scanned into the system via an app through integrated PMR barcodes. The driver scans these barcodes and confirms patient details with the patient/representative at the point of delivery, the software also records geolocation tags, photographs, time of delivery, signatures, failed deliveries and safeplace deliveries. The software meets all legal, GDPR and security requirements for handling patient data. All delivery preferences consented and agreed with the patient are also saved onto the system and only allow the driver to deliver within the legal parameters set by the pharmacy and agreed with the patient for example the system does not allow delivery of CDs without the patient or nominated representatives signature. These are accessible and checked by the RP daily via audit reports including CD delivery audit on the Pharmdel website dashboard. Local delivery staff are fully trained using accredited courses and company materials to ensure safe and effective deliveries.

Local cold chain deliveries involve the use of a calibrated portable medical fridge in conjunction with a built-in digital temperature logger and a standalone remote connectivity enabled cloud based calibrated digital temperature logger to ensure cold chain compliance by maintaining and monitoring temperature between 2 and 8 degrees Celsius. The portable fridge is not designed to be constantly in use, therefore it is plugged into the local power supply at the pharmacy an hour before the delivery drivers' route is expected to begin in line with the manufacturer's instructions, to allow it to reach the correct temperature range. The range is then checked via the built in temperature logger (max, min and current temperature) and recorded by the RP onto the Pharmsmart software under the portable fridge log to ensure that the correct temperature of between 2 and 8 degrees Celsius is being maintained.

All cold chain deliveries are prioritised during the route making process. As with all local deliveries the patient is informed via text/email of the date and time of day the delivery driver will be delivering. Particularly in regards to deliveries involving cold chain items the driver rings the patient to inform/confirm the estimated date and time of delivery before the medication is taken on the route to reduce the chance of delivery failure.

When the delivery driver is ready to leave on his route, cold chain items are added to the portable fridge. The standalone remote connectivity enabled cloud based calibrated digital logger is attached and its probe added to the fridge at this point. This particular logger records and uploads temperature data continuously to a cloud-based web service, giving a complete record of cold chain monitoring for the full duration of the delivery process from start to finish. The portable fridge is unplugged from the local power source, taken to the vehicle and immediately plugged into the car's power source, temperature on the fridge's built in temperature logger is rechecked and recorded onto pharmsmart online log sheet by the driver. The driver also checks and logs the portable fridge temperature (max, min and current) onto the pharmsmart online log sheet via the fridge's built in temperature logger, every time he makes a cold chain delivery during his route which is reviewed by the RP at the end of the route in conjunction with the continuous data received from the standalone remote connectivity logger.

Both the built in and standalone temperature loggers have audible alarms for any range breaches. For an added layer of security, the standalone remote connectivity cloud based calibrated data logger also provides breach alerts via remote connectivity (text messages/ email updates) to the driver and pharmacy mobiles and emails.

in case of a breach the driver rings and informs the RP and returns to the pharmacy.

The RP then gains advice from the manufacturers of the items in regards to the nature length of the breach, segregates the affected items if necessary to avoid them being used by mistake, patients are informed and new items dispensed and a new delivery organised.

If a local cold-chain delivery fails due to the patient not being available to accept it, the driver simply brings the medication back maintaining cold chain in the portable fridge and returns the item to the 'awaiting delivery section' of the pharmacy fridge and consequently re-organises delivery for a more convenient date/time with the patient. At the end of every delivery shift, the fridge is returned and checked for damage. The entire process maintains cold chain from end to end, is effective, has a clear audit trail and allows the RP and driver to have complete oversight.

All non-local deliveries (except for cold chain products) are made by Royal Mail and are audited via information stored on the Royal Mail website with information such as signatures, geolocation tags, photographs, time and date of deliveries. All deliveries sent in this manner are checked by the team to ensure that deliveries have been received successfully.

For Royal Mail deliveries the staff text/email the patients advising how their medication has been packaged and what exact service their package has been dispatched with. Large letters format can fit through letter boxes, parcels can be left (if confirmed and consented by the patient prior to any delivery leaving the premises) with neighbours/safe places (not applicable to CDs) if patients are not in, or re-deliveries/collections from depot can be organised via Royal mail website for a more appropriate date. Tracked Royal mail services for Controlled drugs allow the patient to have direct control over delivery day, offer

a time range and delivery preference's while allowing the pharmacy team to ensure that GPS data, signature and image evidence is obtained upon delivery.

If the prescription is for a controlled drug, either the delivery driver is used (for "local deliveries") or a fully tracked service from Royal Mail known as RM tracked 24/48 service is used. For avoidance of doubt, where prescriptions are delivered by the local delivery driver (within a 30-mile radius of the Pharmacy), the delivery driver has a lockable safe in the boot of the car. The driver is instructed never to leave either the safe or the vehicle unlocked at any point during the delivery rounds. The CD deliveries are packaged separately to normal deliveries and marked clearly with CD stickers on the bag and flagged onto the pharmdel system as CD's, all failed deliveries are returned to the pharmacy and brought to the attention of the RP the same day. The driver is also required to sign the back of the CD prescriptions at the pharmacy before the delivery round and ask for ID from the patient or patients nominated representative at the door. Entries into the controlled drugs register on pharmsmart are made when the medication leaves the premises and the driver/courier are entered as the person collecting/delivering. Prescriptions are retained till positive confirmation of delivery for both local/courier deliveries. The Royal mail tracked service offers the patients the ability to track their package via email or text, gives them a delivery time range and allows them to choose the day of delivery. GPS, image and signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery. If the patient misses the delivery, Royal Mail provide a "failed delivery card". A redelivery can then be arranged with Royal Mail online, or patients can contact the pharmacy for advice.

All cold chain deliveries are carried out in accordance with verified and approved cold chain procedures. This ensures 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 service.

Non-local cold chain delivery is handled currently by a dedicated cold chain courier, Igloo, who have verified and approved cold chain procedures and meet the relevant criteria to ensure a fully monitored and dedicated cold chain service.

We aim to review our cold chain courier selection periodically; our current cold chain courier is IGLOO. A technical agreement between Igloo thermo logistics and Healthcare Time LTD is currently in place.

They are MHRA-approved, meaning they meet all the regulatory standards and are therefore able to offer a quality courier service to the pharmaceutical and life science sectors. IGLOO use high specification monitored refrigerated vehicles and have refrigerated storage facilities. They offer an end to end dedicated, temperature controlled and fully monitored cold chain courier service. All breaches of cold chain sent in this manner are notified to the driver/relevant person and any affected deliveries cancelled and pharmacy informed of the cold chain breach.

The patient is contacted once their prescription arrives to ascertain their availability to accept delivery of the cold chain medication. It is re-iterated to the patient that they must be available to accept and sign for the parcel due to its nature or make arrangements to have it delivered to an alternative address such as their office or work place if appropriate. The patient is informed that if they miss the delivery, they must organise a re-delivery.

They are also told that they will be updated as to the tracking data of their parcel via email notification.

The team ensures that any cold chain item prepared for delivery via the courier is kept in the 'awaiting delivery' section of the fridge, any accompanying items are marked with a fridge line sticker and information sticker that the cold chain item will be delivered separately via cold chain courier.

Once the patient has agreed and is fully made aware of the date the package will be delivered, the IGLOO cold call delivery is initiated via email ordering and relevant temperature range of 2 to 8 degrees Celsius, with required delivery date, address and weight is input. The item is packaged in a reinforced cardboard box with Styrofoam to protect it during transit and the box then remains in the 'awaiting delivery section' of the pharmacy fridge till the courier arrives to collect and upon hand over it is reconfirmed that the temperature range of 2 to 8 degrees will be maintained end to end. The item is then collected, the patient receives all of the tracking data and updates. Staff then monitor the tracking and delivery status of the package the next day till positive confirmation by way of electronic proof of delivery including signature is confirmed. Full temperature logs end to end are kept by the courier for each delivery.

If a delivery is unsuccessful the pharmacy is informed and the courier leaves a failed delivery card stating details of the failed delivery such as date, time and contact details for re delivery requests. The item is taken back to the courier's warehouse for storage before re-delivery, cold chain is maintained throughout. In conjunction with the courier, we have a 72-hour maximum window for cold chain deliveries, the cold chain is kept intact until successful delivery to the patient. If 72 hours have passed without successful delivery to the patient, the courier returns the items to the pharmacy instead, while maintaining cold chain. Pharmacy will immediately get in touch with the patient and organise a re-delivery using the same dedicated courier service for a more convenient date.

All breaches of integrity of cold chain are monitored and detected via the processes put in place by us and the dedicated cold chain courier at every stage of the process. These systems also make the driver aware if there have been any breaches automatically. If such an event takes place, the driver will leave a failed delivery card at the patients address citing breach of cold chain as the reason and the pharmacy will also be notified. The stock with breached integrity will be returned to the pharmacy and will be segregated from the pharmacy stock to avoid the risk of being used again. Pharmacy will immediately get in touch with the patient and organise a re-delivery with new stock using the dedicated courier service.

The process places emphasis on preparation, ability to communicate with the patient prior to delivery, valuing the patient's delivery preferences, end to end cold chain monitoring and efficient delivery to ensure cold chain is maintained. We are also fully prepared to deal with any breaches to ensure patient safety."

6.63 Whilst the Committee noted the comments from the Appellant with regard to the "portable medical fridge" in respect of deliveries where the 'cold chain' needs to be maintained, the Committee considered the information provided by the Applicant in their application form with regard to "local cold chain deliveries" as set out above. The Committee noted the use of specialist couriers as well as how the temperature would be monitored throughout transit up to the point of delivery, especially when the local delivery driver might be used. The Committee was of the view that it had been provided with assurances that the integrity of local cold chain deliveries would be maintained.

6.64 The Appellant had also raised concerns about a "safe place" for deliveries that a patient is unable to physically accept and submits that this is unlikely to be appropriate for

medicines or be considered “safe and effective”. The Committee considered the information provided by the Applicant stating that any Royal Mail ‘safe place’ has to be confirmed and consented to by the patient prior to any delivery leaving the premises, and further that the Applicant has confirmed ‘safe places’ would not be used for deliveries of controlled drugs.

6.65 Based on the information before it, 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.

6.66 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.

6.67 In relation to appliances, the Applicant in its application form stated “none” in response to the question of whether they are undertaking to provide appliances. The Committee noted that under the heading “signposting” in the application form, the Applicant had further stated “*We do not provide an appliance service and follow the terms of service in regards to referral/signposting of such patients.”*

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

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

6.70 In the application form, the Applicant had stated:

6.70.1 *“Choice of packaging is subject to the type of the items and type of delivery. Our packaging has correct levels of protections to ensure item integrity and ability to withstand delivery processes. We attach tamper proof seals to our packaging to ensure that when the patient receives the package, they can be confident that it has not been tampered with.*

For non-fragile local deliveries, we package using pharmacy bags supplied for standard prescription items. For fragile items we use sealable bubble wrap pouches which are then packaged into re-enforced heavy duty cardboard boxes. Fragile stickers are added to make the driver aware so he can handle the package with extra care. CD stickers are added to all CD items which are packaged individually into the standard pharmacy bags with tamper proof seals and kept in the cabinet. For Local Fridge items, items are placed into plastic pouches, post delivery storage condition instructions are added to the pouches and tamper proof seals and fridge item stickers are added. These are then stored in the awaiting delivery section of the fridge in the pharmacy till they are ready to be moved to the portable fridge prior to the delivery round.

For non-local Cold-Chain items, the item/items are placed in bubble wrapped pouches and any instructions on storage conditions post-delivery for the patients to follow are also added to the pouch. This is then placed into to the Styrofoam filled re-enforced cardboard boxes, fridge line and fragile stickers are attached to the outside of the box. The box is then stored in the awaiting delivery section of the pharmacy fridge till it is handed over to cold chain courier. The cold chain company ensures the cold chain integrity from end to end by maintaining a range of 2 to 8 degrees Celsius. The company uses fully monitored vans and warehouses with cold chain sections to protect the integrity of the box/boxes and its contents to ensure it reaches the patient without any breach. All of our staff which handle the packaging of cold chain items are fully trained and understand that thermolabile products can get damaged from excessive temperatures both hot and cold.

For postal items - All of our packaging is completely discreet and of the highest quality and is selected to fit the type of medication posted.

Non-Fragile items - Heavy duty Padded bubble lined envelopes of different sizes are used dependent on the number of items that need to be posted to ensure manufacturers packaging integrity. If the items cannot fit into padded bubble envelopes, then we use a combination of bubble wrap around the items with cardboard protecting matting filler or biodegradable loose fill chips within re-enforced heavy duty cardboard boxes.

Fragile items - All large or fragile medicines such as creams/bottles are packaged with a combination of bubble wrap around the items either in a pouch format or loose bubble wrap. These are then placed into heavy duty re-enforced cardboard boxes and the voids are filled with cardboard protecting matting filler or biodegradable loose fill chips to protect during transit. Fragile stickers are added to the outside of the boxes to make the courier handle the package with extra care."

6.71 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

6.72 The Committee asked itself how the Applicant will be satisfied when dispensing a repeatable prescription other than on the first occasions, 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 has been no changes to the patient's health, which may indicate the desirability to review the patients treatment.

6.73 The Committee noted that in the application form, the Applicant had stated:

6.73.1 *"Where Serious Shortage Protocols (SSP) has been issued, medicines not available or in short supply by the manufacturer, the SSP is followed to provide an alternative under the protocol. The patient is contacted via telephone to ensure they understand the change and ensure the patient knows how to use their medicine correctly. The patient is also informed of what to do if they experience any problems with the alternative medicine. Finally, the patient's GP is also informed of any adjustments made under the SSP. Prescriptions are endorsed accordingly and the prescriber notified."*

6.74 And further:

6.74.1 *"Medication on each occasion is only supplied where the pharmacist is content via a non-face to face consultation with the patient that the patient is taking and will continue taking the medication appropriately, is not getting any side effects and there have been no changes to their medicine regime or their health. If side effects or any reason is identified that the service might no longer be appropriate for the patient, the pharmacist immediately raises this with the prescriber through channels like a referral form, email or phone to allow a holistic review to take place of the patient's treatment and clarity around appropriateness of further supplies is sought. If changes are made by the prescriber such as a change of dose, quantity or stopping a medication, this is communicated to the patient via email/phone and information recorded into their PMR and repeat dispensing record."*

6.75 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

6.76 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of long term 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.

6.77 The Committee noted in the application form, the Applicant had stated:

6.77.1 *"Repeat dispensing is provided according to the NHS Terms of Service.*

Appropriate patients (with long term, stable medical condition/conditions) are identified (with regard to the Terms of Service) and advice is given about the benefits of this service via telephone, email, website or via the appropriate leaflets. Patients are reminded that they should only request items which they actually need.

Any dispensing of repeat NHS prescriptions and dosette dispensing as may be required under the Equality Act, is done via consultation of patients, prescribers and carers via telephone or other non-face to face contacts. These are requirements in addition to requirements for dispensing and assessing the patients' need for repeat supply. Issues identified of a clinical nature are addressed with the prescriber.

Medication on each occasion is only supplied where the pharmacist is content via a non-face to face consultation with the patient that the patient is taking and will continue taking the medication appropriately, is not getting any side effects and there have been no changes to their medicine regime or their health. If side effects or any reason is identified that the service might no longer be appropriate for the patient, the pharmacist immediately raises this with the prescriber through channels like a referral form, email or phone to allow a holistic review to take place of the patient's treatment and clarity around appropriateness of further supplies is sought. If changes are made by the prescriber such as a change of dose, quantity or stopping a medication, this is communicated to the patient via email/phone and information recorded into their PMR and repeat dispensing record.

All interventions, consultations, records and information of supply are recorded into the patients PMR and repeat dispensing record for future reference."

6.78 Given the information above, 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

6.79 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.

6.80 The Committee noted in the application form, the Applicant had stated:

6.80.1 *"The disposal of unwanted medicine service is advertised on the pharmacy website and on the practice leaflet. Patients or their representatives cannot return any medicines directly to the pharmacy and the team follows our procedures to ensure safety & avoid any face-to-face contact.*

To arrange the return of unwanted medicines to the Pharmacy the patient telephones and speaks to a member of the dispensary team. For controlled drugs this is always the pharmacist on duty.

Unwanted medicines from patients, children's homes and residential care homes are collected by the designated driver if local or via a tracked return service from Royal mail via pre-paid packaging. Returns are then segregated and stored accordingly in containers provided by the approved waste disposal contractor, contracted by the local NHS England Team. The waste contractor (PHS) collects the unwanted medicines as per their procedure.

Return and destruction of Controlled drugs are carried out in accordance to the GPhC guidelines. Where waste is a controlled drug, this requires a Royal Mail pre-paid tracked signed for return service. The controlled items returned by the patient are then segregated from the rest of the controlled drugs, labelled "patient returned" and stored in the controlled drug cabinet until destroyed by an authorised witness and the responsible pharmacist. All CD returns are signed for, recorded on the CD destruction register, labelled as CD returns, segregated & stored correctly in accordance with legislation to await destruction.

Where the patient needs to return any sharps or clinical/contaminated waste they are informed of the local procedures for disposing of them. The pharmacy staff sign-post the patient to the relevant services.

Staff are informed of the risks of handling waste drugs and the correct procedure for handling those drugs and are provided with suitable protective equipment and materials to deal with spillages.2

6.81 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13-15 of Schedule 4.

Promotion of healthy lifestyles

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

6.83 In its application, the Applicant states:

6.83.1 *"The provision of opportunistic healthy lifestyle advice is provided via telephone, writing/email or via the pharmacy website. There is pro-active participation and contribution to agreed national and local health campaigns. Leaflets and/or information packs are sent via the dispensed medicines bags or delivered per patient request. Social media campaigns on the pharmacy social media channels are also shared. Records are made of participating in health campaigns as required."*

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

Prescription linked intervention

6.85 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.

6.86 In its application, the Applicant states:

6.86.1 *"The pharmacy also pro-actively targets relevant patient groups, as appropriate, with healthcare advice through prescription linked interventions where a patient presents a prescription and it appears that the patient has diabetes, is at risk of coronary heart disease (especially those with high blood pressure), or smokes or is overweight. Records of interventions are made as required. Identification of patients takes place through three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process. This is through the use of lifestyle questionnaires available via email or sent to the patient and returned by post, during interactions e.g., remote advice consultation or the repeat dispensing process which will indicate what conditions a patient suffers from. Advice is backed up with written material (sent by email or post or with the patient's medication) or by referring the patient to other sources of information or advice as appropriate.*

All lifestyle interventions are recorded on the patient's PMR including the information provided by the patient and the information given to the patient, as well as any written materials that have been provided. All lifestyle interactions, advice (and requests for advice) operate without face-to face interaction (e.g., telephone, email, Skype, WhatsApp and via the website). Advice and help is 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."

6.87 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

6.88 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. In its application, the Applicant states:

6.88.1 "*We participate in health campaigns as requested by the NHSCB, including through information provided on leaflets with prescriptions, the website and information is given to patients both opportunistically (where contact is made with patients through email, phone or WhatsApp, all contact is non-face to face) and in response to the dispensing service to ensure they are kept up to date in regards to [sic] the campaigns.*

Patients are also evaluated for participation in a minimum of at least one clinical audit and whichever of the following as per NHCB specifications. Clinical audit is executed in compliance with NHCB's arrangements of receiving and processing data from the audit. Policy audit (to help development of the commissioning policies) is executed in compliance with NHCB's arrangements of receiving and processing data from the audit."

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

Signposting

6.90 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. In its application, the Applicant states:

6.90.1 *"Further help or advice beyond the pharmacy input is provided on the pharmacy website. This includes details of local and national health and social care organisations and any NHS England recommended groups to provide support to patients. Information is also provided via email and telephone*.

Patients are signposted to other health and social care professionals where this is appropriate via telephone, email, letter and written literature, and information on the pharmacy website. The pharmacy's website will contain links to other health care providers & also an A-to-Z healthcare section."

6.91 And further:

6.91.1 *"We do not provide an appliance service and follow the terms of service in regards to referral/signposting of such patients."*

6.92 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

6.93 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families. In its application, the Applicant states:

6.93.1 *"Patients are provided with advice and support to help them look after their own health, especially on managing minor ailments, common conditions and long-term conditions. Appropriate advice on OTC medicine usage is provided via the website. Telephone, email & video call consultation is also available. Appropriate records are kept as required."*

6.94 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

6.95 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.

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

6.97 In its application, the Applicant states:

6.97.1 *"The DMS procedure covers all the stages & regulations in detail. Referrals are made to the pharmacy via secure electronic message via pharm outcomes. A notification email is sent to the pharmacy email address which is accessible by staff and is checked at least 3 times a day. Referrals are actioned within 72 hours of receipt. Consent is taken by the referring trust & patients can withdraw consent in any stage.*

Stage1 - Receipt of discharge referral

Patient details are checked, medicines on discharge are compared with admission via PMR & SCR. Any concerns are raised with the NHS trust & patient GP, notes are added to the PMR. Alerts are set to conduct stage 2 & 3 when the first prescription or contact is received. Any previous prescriptions are returned to spine if not appropriate for supply.

Stage2 - Receipt of first prescription following discharge

Pharmacist compared the discharge referral with the post discharge prescription to ensure no discrepancy. If one is found a referral is made to the GP to resolve any issue and records are made on the PMR. If consent is revoked in either stage 2/3/ prescriptions are not received or no contact is made with the patient after a reasonable number of attempts, concerns are relayed to the GP.

Stage3 - Shared decision-making discussion with patient

Patient knowledge of what medication they are taking & how they are supposed to be taking is checked, any gaps in knowledge are filled with advice. The conversation is confidential & provided via phone/video consultation. The patients PMR is updated & with the patients consent any information of value is shared with the GP/PCN to support the patients on going care. Patient is also offered the return service for any unwanted medicines & also the NMS service if relevant.

The procedure also deals with issues such as patients moving community pharmacies after stage 1, temporary closures and record keeping & payment. At the end of each month, for each DMS provision a report of standard dataset is submitted via MYS for payment."

6.98 Based on the information provided, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

6.99 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.

6.100 The Committee noted references throughout the application form and supporting information with regard to the use of the website. In addition the Applicant states:

6.100.1 *"The pharmacy provides the public with access to pharmaceutical services from the pharmacy premises through the website www.timepharmacy.co.uk which includes an interactive page (https://timepharmacy.co.uk/health-promotion-zone/) that is clearly promoted to any user of the website when they first access it, this provides the public with access to a reasonable range of up-to-date materials that promote healthy lifestyles by addressing a reasonable range of health issues. This is a new requirement under the Regulations that does not allow for face-to-face access to essential pharmaceutical services at the premises and only applies to access via the website."*

6.101 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

6.102 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).

6.103 The Committee therefore determined that it was not required to refuse the application under Regulation 24(3)(d).

Overall

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

6.104.1 confirm the Commissioner's decision;

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

6.104.3 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.

6.105 As the Commissioner did not consider Regulation 24(2) and had stated in their decision letter that it was "not applicable" although the application is for a relocation from one HWB area to a neighbouring HWB, the Committee determined that the decision of the Commissioner must be quashed.

6.106 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.

6.107 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.

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

7.3 The Committee has determined that the conditions set out in Regulation 24(2) (a), (b), (c), (d), (e), (f) and (g) are satisfied.

7.4 The Committee has determined that it was not required to refuse the application under Regulation 24(3)(d) after considering the grounds set out in Regulation 25.

7.5 The application is granted.

Case Manager
Primary Care Appeals