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4 October 2023

REF: 26052

APPEAL AGAINST NHS HERTFORDSHIRE AND WEST ESSEX ICB DECISION TO REFUSE AN APPLICATION BY MEDSTONE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 110 BUTTERFIELD INNOVATION CENTRE AND BUSINESS BASE, GREAT MARLINGS, LUTON, BEDFORDSHIRE LU2 8DL UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Medstone Ltd
Primary Care Support Services, on behalf of Hertfordshire and West Essex ICB

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1 The Application

By application dated 2 February 2022, Medstone Ltd ("the Applicant") applied to NHS England for inclusion in the pharmaceutical list at 110 Butterfield Innovation Centre and Business Base, Great Marlings, Luton, Bedfordshire LU2 8DL under Regulation 25. In support of the application it was stated:

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

1.1.1 Dressings

1.1.2 Hosiery and compression bandages

1.1.3 Catheter appliances

1.1.4 Incontinence appliances including sheaths and catheter bags

1.1.5 Stoma appliances

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

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left the section blank.

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

1.4 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.

1.5 There will be a responsible pharmacist (RP) on site at all times during the opening hours. The RP will not be allowed to leave the premises unless a second pharmacist is present on the premises. If the RP has to leave the premises or wants to take a break, then a second pharmacist on the premises must sign in as RP and clearly display their RP notice. The RP will leave their contact details in case they need to be

contacted by a member of staff. If the absence from the premises exceeds 2 hours then the second pharmacist must assume the role of RP and notify the superintendent.

1.6 The safe and effective provision of essential services without face to face contact between any persons receiving the services will be provided by telephone, email (NHS email and/or customer service email for the pharmacy) which will be monitored on a daily basis. A GPhC compliant website promoting healthy lifestyles that allows patients to order repeat medication. Prescriptions will be received via Electronic Prescription Service (EPS), fax and as hand written or printed prescriptions. Envelopes with return address of the pharmacy with first class stamps will be sent to surgeries for them to send prescriptions to the pharmacy. Medication up to a 30 mile radius will be delivered by a delivery driver and any area after this will be delivered via Royal Mail to all patients in England. Controlled drugs will be delivered by a controlled drug courier and fridge lines will be delivered by a cold chain courier. Pharmacist will telephone or video call patient after delivery to counsel [sic] them on the correct usage of their medication. PHS group will collect clinical waste from patient's homes. Explain to patient due to NHS regulations the Applicant cannot provide face to face provision of NHS essential services and give patients contact details of a suitable service provider using NHS Choices website. There will be an allocated time slot for the advanced service only, patient will be made aware of this.

2 **The Decision**

NHS Hertfordshire and West Essex ICB ("the ICB") considered and decided to refuse the application. The decision letter dated 25 June 2023 states:

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

2.1 NHS Hertfordshire and West Essex ICB has considered the above application and [is] writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

2.2 You have a right of appeal to the Secretary of State against NHS Hertfordshire and West Essex ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or: Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU.

Decision report

2.3 The Committee considered this excepted application in respect of distance selling premises, which is determined under the following regulations:

2.4 **Regulation 31:**

2.5 The Committee noted that there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from the premises to which the application relates or adjacent to the premises.

2.6 The Committee was therefore not required to refuse the application under the provisions of Regulation 31.

2.7 **Regulation 25:**

2.8 The Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including Standard

Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

2.9 The Regulations required the Committee to be satisfied that essential services will be provided on an uninterrupted basis, to persons anywhere in England, in a safe and effective way, and without face-to-face contact.

2.10 The Committee noted that the opening hours declared on the application form total 40 core hours per week, and are listed as Monday to Friday 09:00-17:00.

2.11 To provide an uninterrupted service, the applicant had stated in their application that there will be a responsible pharmacist (RP) on site at all times and the supporting document stated that there will be two pharmacists present during their core hours. If the RP needs to leave the premises the second pharmacist will sign in as RP.

2.12 The Committee noted that SOPs were supplied within the supporting documentation. The applicant had detailed how they will secure safe and effective provision of essential services without face-to-face contact to persons anywhere in England. Patients will be contacted via email, text, telephone or video call. Medicines will be delivered via courier.

2.13 **Representations**

2.14 The Committee noted the representations/comments made by:

2.14.1 Bedfordshire Local Pharmaceutical Committee (Beds LPC)

2.14.2 Boots UK Limited

2.15 The Committee also noted the response from the applicant.

2.16 **Decision**

2.17 The Committee considered the application and agreed as follows.

2.17.1 The Committee were satisfied that the application meets the tests of Regulation 31.

2.17.2 The Committee were satisfied that the proposed premises are not adjacent to or in close proximity to other chemist premises.

2.17.3 The Committee were satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.17.4 The Committee were satisfied that all essential services were likely to be secured without interruption during the opening hours.

2.17.5 The Committee were satisfied that all essential services were likely to be secured for persons anywhere in England.

2.17.6 The Committee agreed the applicant states that appropriate packaging is used but has not explained what it is.

2.17.7 The Committee agreed the fridge line deliveries have not been satisfactorily explained on hand over to patients.

2.17.8 The Committee were not satisfied that all essential services were likely to be secured in a safe and effective manner.

2.17.9 The Committee were satisfied that all essential services were likely to be secured without face-to-face contact.

2.18 The Committee refused the application.

2.19 Whilst the Committee were satisfied that some aspects of the regulations were met, it refused the application as they were not satisfied that all essential services were likely to be secured in a safe and effective manner.

2.20 The Committee agreed that appeal rights are given to the applicant, Medstone Ltd.

3 The Appeal

The Applicant appealed against the ICB's decision by way of the 'On line form for pharmacy application appeals' dated 3 July 2023. The grounds of Appeal are:

3.1 The Applicant is appealing against NHS Hertfordshire and West Essex ICB's decision. The grounds of appeal are based on the Applicant can satisfy NHS England that all essential services will be provided safely and effectively without face-to-face contact with anyone in England without any interruptions. The Applicant sees no reason for the application to be rejected as it believes it can prove all rules and regulations regarding a distant selling pharmacy will be adhered to. The Applicant believes it can be an asset to NHS and provide NHS services from afar to all patients in England, helping to alleviate the growing pressures GPs are facing. The grounds of appeal also are that the Applicant has reviewed and amended its SOPs to address the missing information and the below concerns raised by the Committee:

3.1.1 The Committee agreed the Applicant states that appropriate packaging is used but has not explained what it is.

3.1.2 The Committee agreed the fridge line deliveries have not been satisfactorily explained on hand over to patients.

3.1.3 The Committee were not satisfied that all essential services were likely to be secured in a safe and effective manner.

3.2 Please see attached documents for:

3.2.1 Appeal letter/supporting document, which states the grounds of appeal and addresses the concerns raised, which led to the original application to be rejected.

3.2.2 All current SOPs have been provided to support the application/appeal.

3.2.3 Floor plan

3.2.4 The letter provided to Market entry to address the concerns of Boots, Lloyds and Bedfordshire LPC

3.3 The Applicant has supplied all information and documents, some of which may be seen as unnecessary but it did not want to assume NHS Resolution has been given all the information/supporting evidence, therefore the Applicant has attached everything relating to this application.

Appeal letter/Supporting document

3.4 **Appeal of application for inclusion in the pharmaceutical list at 110 Butterfield Innovation Centre and Business Base, Great Marlings, Luton, Bedfordshire, LU2 8DL in respect of a distant selling pharmacy.**

3.5 An appeal for a new pharmacy contract in respect of a distance selling premises and as such is an excepted application under regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 has been submitted.

3.6 The Applicant is appealing against NHS Hertfordshire and West Essex ICB's decision. The grounds of appeal are based on Medstone can satisfy NHS England that all essential services will be provided safely and effectively without face-to-face contact with anyone in England without any interruptions.

3.7 The Applicant asks that the Secretary of State, NHS Resolution to take into account the additional information included in this appeal letter/supporting document and the attached amended draft standard operating procedures (SOPs) to address NHS Hertfordshire and West Essex ICB's concerns when considering its application for inclusion in the pharmaceutical list. The Applicant firmly believes if this application is granted, it will be able to deliver the Essential Services to any patients in the UK without face-to-face contact. The Applicant's robust working practices and standard operating procedures will ensure 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.

3.8 NHS Hertfordshire and West Essex ICB have refused the Applicant's application based on:

3.8.1 "The committee were not satisfied that all essential services were likely to be secured in a safe and effective manner"

3.8.2 "The Committee agreed the applicant states the appropriate packaging is used but has not explained what it is."

3.8.3 "The Committee agreed fridge line deliveries have not been satisfactorily explained on hand over to patients."

3.9 The Applicant believed it had provided all the information required to show that it will secure all essential services in a safe and effective manner, especially as the director Sarah Hussain has worked as a superintendent pharmacist in a distant selling pharmacy for over 3 years, gaining sufficient knowledge on the rules and regulations of running a distant selling pharmacy without breaching any of these rules and regulations set out by NHS. However, NHS has pointed out important information that was missing, as mentioned above. The Applicant will address these concerns in this appeal letter and supporting document, including SOPs.

3.10 **Overview**

3.11 The Applicant wishes to secure inclusion in the Pharmaceutical List to deliver NHS Services via a distant selling pharmacy, providing service to the whole of England without the need for face-to-face contact. The Applicant plans to provide medication in a managed way that makes obtaining regular medication as well as acute medication from a pharmacy as stress free as possible. The Applicant's business model is to help those who are less able to access medication locally due to their lifestyle options, medical conditions and those who are high-risk patients and advised to shield. The Applicant's website will be available to the patients 24 hours a day 7 days a week to aid it to provide an efficient service that will service the whole of England without the need for face-to-face contact.

3.12 The Applicant will primarily focus on imbedding Quality Management System and Essential Services delivery in the first year. Once the Applicant has established a robust customer base and are positive, it is delivering this to an exceptional standard then the Applicant's focus will move towards offering Advanced and Enhanced Services through its distant selling pharmacy.

3.13 In making this application, the Applicant is aware of the requirements in operating a Distance Selling Pharmacy and will be complying with the relevant legislation. The Applicant will ensure that it subscribes to the Royal Pharmaceutical Society and join the National Pharmacy Association as well as GPhC updates and the Applicant will make sure it abides by the Good Pharmacy Practice. The Applicant aims to abide by all the NHS terms of service and fully adapt to them. The Applicant will ensure the pharmacy is equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality. The Applicant will ensure it operates the pharmacy in accord with current GPhC guidance for registered pharmacies providing services at a distance, including the internet. The Applicant will be GPhC compliant.

3.14 **Information in support of the application**

3.15 Under the regulations we need to explain how the pharmacy procedures used within the premises will secure:

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

3.15.2 (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 someone else's behalf, and the applicant or the applicant's staff.

3.16 *Essential Services 1 – Dispensing* – ***Please refer to MS-SOP-V04.1 - SOP for Supply of Medicines***

3.17 "The supply of medicines and appliances ordered on NHS prescriptions, together with information and advice, to enable safe and effective use by patients and carers, and maintenance of appropriate records."

3.18 The pharmacy will provide dispensing of NHS medicines safely via [paragraphs 3.19 to 3.108].

3.19 All new patients will register with the Applicant's Pharmacy website designed by The Pharmacy Centre (which will be GPhC approved and compliant). Patients will be asked to complete a consent form making them aware Medstone is a distant selling pharmacy and the Applicant's services will be provided from afar and that they agree to their medication being dispensed and prepared without any face-to-face contact. They will also have to fill out a short questionnaire about their medical history and any other medication they may be taking. Hard copies of this will be stored securely in the pharmacy as well as electronic copies that will be saved on the system. If a patient struggles to access the internet/website, then the forms will be posted to them with a prepaid envelope.

3.20 A team of suitably trained staff working to a tailored set of Standard Operating Procedures (SOPs) created by the Superintendent Pharmacist. All team members will be trained according to their role and will be trained in the SOPs before commencing employment and carrying out any tasks.

3.21 Each prescription will be checked by a pharmacist, either the Superintendent, the pharmacist director Sarah Hussain or an employee/locum pharmacist, in accordance with their training and identified best practice.

3.22 If there are any clinical or legal discrepancies, the patient and/or prescriber will be contacted via email, phone or text and steps will be taken to resolve them with promptness as per the relevant SOP.

3.23 Every patient will be contacted via email, text, telephone, or a secure video call for each new prescription where a clinical check will be carried out and the appropriate advice communicated.

3.24 All prescriptions will be dispensed, accuracy checked and clinically checked. Once ready for dispatch the prescription will be packed in validated packaging (***please refer to MS-SOP-V05.1 - SOP for Delivery of Medicines including CD and cold Chain***) and sent to the patient by a local delivery driver up to 30 miles radius (excluding CD and fridge lines) or by City Sprint (including fridge and CD lines), an approved and robust medicines logistics provider. Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection will be used to ensure that the item can withstand the normal rigours of the delivery process. All packaging will have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident. Medicine for local delivery which is not fragile and to be delivered by the delivery driver will be packaged in the using the pharmacy bags supplied for standard prescription items. Medicines classified as non-flammable or non-toxic will be securely closed and placed in a leakproof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids). It will be tightly packed in strong outer packaging and will be secured or cushioned to prevent any damage.

3.25 For most items bubble wrap will be used and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type. Large or any fragile medicines will be packed into cardboard boxes with bubble packaging and filling material to protect from damage. Cold chain items will be bubble wrapped and stored in Styrofoam filled cardboard boxes prior to being passed to the courier and marked with the “FRAGILE” and “FRIDGE LINE” stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored (“cold ship” packaging).

3.26 The patient will be notified of the delivery and upon receipt of delivery a signature will be obtained, therefore the pharmacy will have confirmation of delivery acceptance and an audit trail.

3.27 There will be two pharmacists present during core opening hours, consisting of superintendent and/or the director Sarah Hussain and/or a locum/employee to ensure the uninterrupted provision of essential services during the opening hours of the pharmacy to persons anywhere in England who request any services.

3.28 The Patient Medication Record will be maintained diligently to include all contact details, allergies, known conditions, and carer details. This will also include medication history, interventions; items owed, preferred method of communication, whether patient has a carer(s) that have permission to communicate on behalf of patient, authorised recipients for delivery such as a family member in the same household or a neighbour etc. and any additional communication notes that are needed to ensure safe supply of medication.

3.29 The patients will also have the option to have their medication dispensed in dossette boxes free of charge under the Equality Act 2010 if it is deemed the patient may benefit from this for compliance purposes. This will be assessed without face-to-face contact via phone, secure video call or email/text with either the patient or their carer/representative.

3.30 With each NHS prescription, the patient will be contacted by the dispensing pharmacist via their chosen method (email, text, telephone or video call) about correct medicine

usage, storage and safe keeping of medicines. Where the pharmacist deems necessary, a written note concerning correct usage will be included within the package.

3.31 Any medicines owing will be communicated via phone at the time of receiving the prescription to determine whether dispensing of a part prescription is necessary to start treatment or whether the patient would prefer to be notified via email, text or a phone call when the medication/remaining medication comes in to stock. If the patient prefers to try another pharmacy, then the prescription will be released onto the NHS spine if received electronically. If it is not an electronic prescription, then it will be posted to the patients chosen pharmacy after contacting them. The scanned prescription will be sent via NHSmail of [sic] faxed to the chosen pharmacy to help speed up the process until they receive the original copy through the post. All new customers will be asked if they wish to notify the Applicant of any medications which require special orders that must be ordered in advance to provide continuous future service, which will be noted on the patients PMR.

3.32 Emergency Supply –

3.33 Regarding an emergency supply of medicine requested by patient or prescriber, the responsible pharmacist will assess whether there is an urgent need for medication to be supplied. If this is deemed necessary, the pharmacist will make a supply in accordance with Human Medicines Regulation, maintaining a record on the patients PMR. Due to the nature of the request type, the pharmacy will prioritise this delivery to ensure the patient receives the medication without any delay. If the delivery is up to a 30-mile radius, then the local designated delivery driver will be made aware of its urgency. If this is delivered by CitySprint because it is over the 30-mile radius and/or a fridge line, then the courier will be made aware it needs to be delivered ASAP and to get the medication to the patient via the quickest route. The pharmacy will not charge additional fees to the patient even if these are incurred during the delivery process.

3.34 The medicines packaging used by the Applicant will include clear and precise instructions for patients as to how they can contact the pharmacy for extra advice and help. Where the items (P and GSL medicines) have been bought under pharmacist supervision, via the website, the patient will have an account area where they can also log in and acquire specific details and instructions. There will be links to the website for more advice and to the telephone number if patients prefer.

3.35 Serious Shortage Protocols –

3.36 In case Serious Shortage Protocols (SSP) has been issued, medicines not available or in short supply by the manufacturer, the SSP will be followed to provide an alternative under the protocol. This will be communicated to the patient via telephone or a secure video call to ensure they understand the change and ensure the patient knows how to use their medication safely and correctly. The patient will be informed of what to do if they experience any problems with the alternative medication. They will be advised to contact the pharmacy straight away and/or their GP. The pharmacy will also contact the patient for a follow up just to ensure the patient is not having any issues with the alternative medication. The GP will be informed via writing, email or by phone of any adjustments made under the SSP and if any issues experienced by the patient. All communication notes will be entered on the patients PMR.

3.37 The Responsible Pharmacist will take adequate measures to ensure that the delivery mechanism used, is secure and that medicines are delivered to the patient promptly, safely and in a condition appropriate for use. If the delivery to the patient is local (up to 30-mile radius), then this will be undertaken by the delivery driver except fridge lines and controlled drugs Schedule 2 and 3. All other nationwide deliveries will be carried out by City Sprint including all fridge lines and Controlled drugs schedule 2 and 3 deliveries. All deliveries must be signed for by the recipient.

3.38 When an NHS prescription is received for an appliance, the patient will be contacted via phone, text or email to confirm receipt of prescription. With the patients consent it will be forwarded to a dispensing appliance contractor. The Applicant will set up an account with NWOS and place orders with them directly via telephone, email, or fax.

3.39 Refusal to provide drugs or appliances ordered –

3.40 Where a prescription is received for an item that requires measuring or fitting that patient will be contacted via phone, message or email and informed these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients will be appropriately signposted to at least two other providers of the service in their area. If the prescription is received electronically, it will be returned to the NHS spine for the signposted provider to dispense the prescription for the patient, with patients' agreement. If the prescription has been sent via post, then it will be posted as a recorded delivery via Royal Mail to the signposted provider, which will be agreed with the patient, to ensure no delay is encountered.

3.41 The Responsible pharmacist (RP) will check when dispensing a repeatable prescription, other than the first time, that the patient is still using the medication, not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes to the patients' health. The RP will contact the patient via phone, video call, text or email before each repeat is issued to ensure the patient is taking the medication correctly and still requires it. The pharmacist will ensure the patient is not suffering from any side effects and there have been no changes to the patients' health. This will all be noted on patients PMR and repeat medication will be dispensed and delivered. This will ensure no medicine wastage occurs. Any interventions/referrals to the prescriber or refusal to supply decisions which are clinically significant will be recorded on the Intervention and Referral Form as well as the patients' PMR and will be shared with the patient's GP. (***Please refer to MS-SOP-V10.1 SOP for Repeat Dispensing***).

3.42 Preliminary matters before providing ordered drugs and appliances –

3.43 Evidence of exemption will be checked by the Applicant to ensure the patient is eligible for exemption excluding anyone that is under the age of 16 and the age of 60 or over. Satisfactory evidence will include evidence derived from a check known as a Real Time Exemption Checking (RTEC), which will allow the pharmacy to immediately check if the patient is eligible for free prescriptions.

3.44 Evidence can be sent to the pharmacy via the pharmacy delivery driver which will be returned to the patient. Other than this the patient will be able to fax/email a copy of their exemption to the pharmacy. The pharmacy staff will make a note of the exemption on the patients' PMR with the exemption details, start date and expiry date. For income-based exemptions, the patients will be asked to provide evidence on each occasion to ensure their continued entitlement of their benefits and free prescriptions. The regulations require the patient to produce 'satisfactory evidence' to confirm exemption. Original and/or copies will be accepted. Plastic, paper and digital certificates will all be accepted as proof of exemption if they are valid and in date. The responsible pharmacist (RP) can determine if the evidence provided is satisfactory. In regards to patients who use postal service to post evidence of their exemption status, the pharmacy will advise the patient to use Special Delivery services of recorded deliveries where all cost will be covered by the pharmacy including return of the exemption.

3.45 If the patient must pay for their prescription, then the staff will check the prescription to confirm how many charges are due via phone, text or email. The pharmacy staff will also check to see if any fees have been paid and if so, was the correct amount paid? If the pharmacy believes the patient meets the criteria and can benefit from a prepayment certificate or HRT prepayment certificate, then they will be made aware of this and guided on the steps to obtain a prepayment certificate.

3.46 The pharmacy staff will contact the patient via telephone, email or message to notify the patient to arrange payment using the secure payments system using the, customer not present' (CNP) option. This will allow payment to be taken remotely.

3.47 If no fees have been paid or there is a discrepancy between the fees that have been paid and are outstanding, the patient will be contacted directly via preferred method of contact and directed to pay the correct fees via the secure payment portal on the website. (***Please refer to MS-SOP-V04.1 SOP for Supply of Medicines***)

3.48 Providing ordered drugs and appliances- (***please refer to MS-SOP-V05.1 SOP for Delivery of Medicines including CD and Cold Chain***)

3.49 Upon arrival of the prescription, the patient will be contacted via telephone, WhatsApp/text message or email to ascertain their availability to accept the scheduled delivery. It will be re-iterated to the patient that they must be available to accept the delivery or to make alternative arrangement to have it left with the neighbour. If the patient would prefer to have their medication delivered to a different address if appropriate, such as their work place then this option will be available to them. Under no circumstances will the delivery package be put through a letterbox or left unattended.

3.50 The patient will be given the tracking information, so they can track their medication and ensure they are able to receive the delivery or make arrangements with a neighbour to accept the delivery. Once the patient has agreed and is made fully aware of the date the medication will be delivered, the pharmacy will contact City sprint to initiate the delivery. If the delivery is up to a radius of 30 miles and there are no controlled drugs or fridge lines to be delivered, then the local delivery driver will carry out the delivery. The delivery driver will notify the patient of the approximate time of delivery on the day. The patient will be sent a text reminder/phone call to remind them their delivery is scheduled for the date and time agreed with the pharmacy. All deliveries will require a signature upon delivery to confirm safe receipt of the medicine. The Responsible pharmacist (RP) will oversee and supervise the handing over of all delivery items for delivery.

3.51 All cold chain medication will be delivered by City Sprint and will be stored in the pharmacy fridge and accompanying items will be appropriately marked with a fridge line sticker. The accompanying items will include a note to explain the fridge items will be delivered separately to the rest of their items to maintain the cold chain. 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.

3.52 The pharmacy will provide special delivery instructions, if any to the delivery driver, such as cold chain medication needs to be kept separate and delivered to the patient separately to the rest of the medication and patient will be made aware by both the driver and pharmacy it's a fridge item and what the correct storage instructions are. The patient will be advised to follow the manufactures storage conditions of the medication i.e., keep the cold chain medication in a fridge or below a certain temperature or whether it needs to be kept below 25 degrees or out of direct sunlight etc. This information will be relayed to the patient in more detail by the pharmacist via telephone, message, email depending on preferred method of contact. The driver will make the person accepting the cold chain medication aware of the domestic storage conditions and to follow the manufacturer's instructions on the packaging as well. The responsible pharmacist will contact the patient without face-to-face contact via patients chosen method of communication after medication has been delivered and confirmed, to ensure the patient is aware it is a cold chain medication and needs to be stored correctly per based manufacturer's instructions. The pharmacist will counsel and advise the patient as necessary about their medication.

3.53 If the delivery is unsuccessful, the courier will notify the pharmacy immediately and leave a failed delivery note for the patient stating the date and time of the attempted delivery and contact details of the pharmacy to rearrange delivery. If the patient does not contact the pharmacy within 24 hours, then the pharmacy will make contact with patient via the preferred method agreed with the patient (phone, text or email) to rearrange delivery to ensure patient receives their medication without any delay.

3.54 All cold chain medication will be returned directly to the pharmacy in the instance of a failed delivery however if this is not possible due to the time of day or other external factors due to delay of returning to the pharmacy the same day then the cold chain medication will be stored in City Sprint safe overnight storage facility. Log of temperature can be requested to satisfy the pharmacy the medication has been kept at the correct temperature overnight. All cold chain medication will be stored correctly during transit and a real time temperature log will be used to check temperature throughout the delivery. City Sprint supply validated packing materials for the transit of cold chain medication. This includes ambient packing, the supply of cold chain material for medication that needs to travel in an environment between 2-8 degrees Celsius and dry ice supply, all ensuring correct temperature of cold chain medication is maintained during delivery. However, in the event of any breach in the integrity of cold chain medication during transit or that has been delivered to the patient, they will be contacted and informed to not use any product that may have been affected. The Pharmacy will rearrange immediate re delivery of the item via the same courier and the return of the breached medication. The items that have been subjected to a cold chain breach will not be re used and will be segregated from the pharmacy stock, ready for safe disposal once received by courier.

3.55 Once the SOPs procedure has been followed and the controlled drugs are ready for delivery, the pharmacy will ensure the City Sprint driver signs the declaration on the reverse of the prescription, the driver will be trained to understand their obligations with regards to CD deliveries. The driver will store the CD in the correct area of their vehicle in a secure and locked container. If the delivery is unsuccessful then the CD will be returned to the pharmacy the same day, however if this is not possible due to the time of day then the CDs will be taken back City Sprint CD safe storage location and will await further instructions from the pharmacy. There will be a log made of this on the patients PMR to ensure an audit trail.

3.56 ALL drivers will be trained to lock their vehicle when left unattended.

3.57 The pharmacist will contact the patient without face-to-face contact via phone, video call, message or email to advise them on any relevant messages or counselling that may be needed once confirmation of delivery is received.

3.58 *Essential Services 2 – Repeat Dispensing - (**please refer to MS-SOP-V10.1 SOP for Repeat Dispensing**)*

3.59 "*The management and dispensing of repeatable NHS prescriptions for medicines and appliances in partnership with the patient and the prescriber. This service specification covers the requirements additional to those for dispensing, such that the pharmacist ascertains the patient's need for a repeat supply and communicates any clinically significant issues to the prescriber.*"

3.60 Patients wishing to use the repeat dispensing service who have long term stable conditions requiring regular medication, where there will be no changes from medium to long term will be required to send the Repeat authorisation as well as the Repeat Dispensing Prescriptions to the Applicant via post; a prepaid envelope will be posted out to the patient or pharmacy will receive the RA and RDs electronically or they will be collected from the surgery by the pharmacy. This service will be made available to appropriate patients after having communicated the benefits to them via the approved methods of non-face to face contact via phone, secure video call, message or email. The patient will be advised of the benefits of less regular visits to GPs and not

contacting the surgery/GP at regular intervals to request repeat prescriptions. New patients to the service will confirm that the pharmacy is authorised to retain the Repeat Authorisation and that all the Repeat Dispensing Prescriptions will be dispensed by the Applicant. The patients will be educated on the repeat dispensing service including its benefits and importance of only requesting the medication that is required by the patient to avoid medicine wastage and extra costs to the NHS.

3.61 The pharmacist will contact the patient before each repeat is issued to ensure the patient is taking the medication correctly and still requires it. The pharmacist will ensure the patient is not suffering from any side effects and there have been no changes to the patients' health. This will all be noted on the patients PMR and repeat medication will be dispensed and delivered. This will ensure no medicine wastage occurs.

3.61.1 Any interventions/referrals will be recorded on the Intervention and Referral Form and patients' PMR.

3.61.2 Any dossette dispensing that may be required under the Equality Act 2010 will be done so after speaking to patients/carer and prescribers and assessing the need via telephone or a video call or other preferred non face to face contact.

3.61.3 The pharmacy will contact the patient at least two weeks prior to the finishing of their current prescription and ascertain whether they are still taking their medication, if there have been any changes or any side effects the patient has/is experiencing and whether the repeat medication is to be dispensed. This will all be noted on patients PMR for to ensure an audit trail.

3.61.4 As part of routine communication, any clinical comments from the patient will be relayed, with patient consent, to the prescriber and noted on their PMR.

3.62 All staff including locums will be trained and monitored by the Superintendent Pharmacist for the consistent provision of service in relation to repeat medicines and the relevant SOPs.

3.63 A patient's repeat prescriptions will be stored securely and confidentially on the Patient Medication Record. This will then be maintained at every future event of patient usage. Communication relating to repeat dispensing will encompass continued use of all medications, any new medication being taken, compliant medication usage and any side effects.

3.64 When signing up for repeat dispensing, patients will receive a service consent form for completion via email or post with a prepaid envelope. The pharmacy will also communicate to the patient how the collection of data is utilised. This process will comply with GPhC guidelines on confidentiality and information governance. The pharmacy will have both a clinical governance and information governance lead who will be fully trained in their lead responsibility.

3.65 *Essential Services 3 – Disposal of Unwanted Medicines - (**please refer to MS-SOP-V06.1 SOP for Disposal of Medicines**)*

3.66 "*Acceptance, by community pharmacies, of unwanted medicines from households and individuals which require safe disposal. PCOs will need to have in place suitable arrangements for the collection and disposal of waste medicines from pharmacies.*"

3.67 Patients will be able to safely return unwanted medicines via:

3.67.1 Referring to call-to-action labels, which will be standard packaging on all despatched items.

3.67.2 Contacting the pharmacy and speaking directly to the pharmacist who will be present during all core trading hours.

3.67.3 Referring to the information leaflet published by the pharmacy and then contacting the pharmacy.

3.67.4 Referring to the website information page and then contacting the pharmacy.

3.68 Patients will not be able to return medications directly to the pharmacy.

3.69 Medstone will set up an account with Stericycle healthcare waste management company who will be used to collect patient out of dates or unwanted medications directly from patient's home. Stericycle offer compliant, fully trackable an auditable end to end specialist clinical waste management. Once the pharmacy contract has been secured, terms of service will be integrated into the business model.

3.70 Once a patient has made contact, they will be asked which medication items and amounts they would like to return. Providing there are no needles, sharps or chemicals, for which the patient would have to be signposted for safe disposal, patients will then be advised how to separate the items and pick-ups will be arranged by the pharmacy directly with the healthcare waste management company.

3.71 The Applicant aims to obtain an upper tier 'Waste Carriers License' for any drivers they employ to be able to transport waste medicines from patients' homes to the pharmacy. Direct365 will be used to supply the pharmacy with correct bins for waste disposal collected from patients' homes and any out-of-date medication. The Applicant will contact Direct365 to arrange pick up times of medicine waste for safe disposal; a complete audit trail for all drivers collecting disposable waste will be produced and stored securely in the pharmacy.

3.72 Controlled drugs (schedule 2 and 3) will be made irretrievable and steps will be put in to make a record of the disposal, with respect to safe custody regulations. All patient returned Controlled drugs (schedule 2 and 3) will be placed in a clear bag marked as patient returns and segregated from the rest of the controlled drugs in the CD cabinet, waiting for destruction.

3.73 *Essential Services 4 - Public Health (Promotion of Healthy Lifestyles) - Prescription linked intervention - (**please refer to MS-SOP-V14.1 SOP for Promoting Health Lifestyle**)*

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

3.74.1 *have diabetes; or*

3.74.2 *be at risk of coronary heart disease*

3.74.3 *have high blood pressure; or*

3.74.4 *who smoke;*

3.74.5 *are overweight,*

3.75 *and pro-active participation in national/local campaigns, to promote public health messages to general pharmacy visitors during specific targeted campaign periods.*"

3.76 Patients will be encouraged to lead a healthy lifestyle via:

3.76.1 The Applicant's website which will include general health information as well as information regarding specific public health campaigns, where there will be an interactive page clearly promoting to any person to access the website.

3.76.2 The website will have up to date materials that promote healthy lifestyles by addressing reasonable [sic] range of health issues such as diabetes, heart disease, blood pressure etc.

3.76.3 Information will be provided without face-to-face contact on the pharmacy's GPhC approved website and relevant links will be provided to the patient via text/email, this will make sure patients are able to always access information about health campaigns.

3.76.4 The pharmacy will be proactive in national promotions and engagement in several health-related strategies. Potential topics include Change4Life, Be Clear on Cancer and Flu Immunisation.

3.76.5 Additional further topics as detailed by the host Health and Wellbeing Boards. Potential topics include Stop Smoking and Emergency Hormonal Contraception (EHC).

3.76.6 Patients will have access to a pharmacist via email, text or telephone during the core opening hours. Outside of core hours patients will be signposted accordingly via the website, which will have links for more information.

3.77 The pharmacy will participate in up to 6 health campaigns at the request of NHS England. The pharmacy will pro-actively take part in national health campaigns/community engagement to promote public health messages to patients.

3.78 During the campaign any relevant patients who will benefit from further information will be identified. A record will be made on their PMR to show they have received information as part of the campaign.

3.79 All new patients will complete a health questionnaire upon registration via the website or forms will be sent out to patients with prepaid envelopes if they cannot access the website. The health questionnaire will be used by the pharmacist to complete an initial health profile of the patient. Patients who choose to access the Lifestyle questionnaires (active) via the website and return them by post and are identified from the results as patients who need further information who will be called by the responsible pharmacist to offer additional information and support. This profile will be risk assessed and developed over time to make targeted recommendations to promote healthy lifestyles. This will be recorded on the patient's PMR and monitored.

3.80 Patients will also be identified through the dispensing of prescriptions depending on what medication they are being prescribed (passive patients), will be contacted via phone, message or email and be provided with specific additional information and support regarding their condition. All communication will be noted on the patients PMR.

3.81 The pharmacy will utilise NHS Choices as a national directory of health and support services. A broad range of leaflets will be available for the pharmacist to include within the dispensed prescription tailored to the patient's condition for example an 'asthma' leaflet will be sent to a patient who has been prescribed inhalers/asthma related medication. These will also be available, where practicable, online in the form of a PDF.

3.82 The 'Promotion of Health Lifestyles' web pages will be updated via recommendation from NHS England and the host Health and Wellbeing Boards.

3.83 *Essential Services 5 - Signposting - (**please refer to MS-SOP-V17.1 SOP for Safeguarding and Signposting**)*

3.84 "*The provision of information to people visiting the pharmacy, who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person. Where appropriate, this may take the form of a referral.*"

3.85 Patients will be signposted to other health services via:

3.85.1 The Applicant's website, which will contain information that will signpost patients to healthcare pages such as NHS choices if they require more information regarding a certain ailment, as well as containing useful numbers for the patient to contact if necessary. All the website pages will urge patients to contact the pharmacy directly first via the contact details provided within the core opening hours if they have any concerns, questions or require any information.

3.85.2 Patients will be able to request for a video call via Zoom, Whatsapp, Skype (depending on patients' preference) on the website which will be available during core opening hours. Video call will be at patient discretion and may be requested by the pharmacist whereby a visual of the symptoms and/or affected area may be necessary. Patients will be able to request to book a consultancy time in advance to be able to speak with a pharmacist via the website.

3.85.3 The pharmacy will utilise NHS Choices as a national directory of health and support services which will be used to assist in patient referrals based on patient location.

3.85.4 Specific pharmacy packaging will be created with space dedicated to National support services and the pharmacy website.

3.85.5 Out of core pharmacy hours, patients will be directed to NHS 111 online in accordance with the guidelines.

3.86 The pharmacist-on-duty will complete a communication sheet with all patients at the point of contact and will be trained to make signposting recommendations based on the content of the form. The pharmacist will follow the SOPs for signposting. All details will be recorded in the patients PMR.

3.87 All employed pharmacists will undergo the required amounts of annual CPD training so the pharmacists can continue to make signposting recommendations for any patients of the pharmacy.

3.88 *Essential Services 6 – Support for Self Care - (**please refer to MS-SOP-V18.1 SOP for Support of Self Care**)*

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

3.90 Patients and carers will be given appropriate advice on managing illness, both immediately, and for the future, via:

3.90.1 Sales to patients of non-prescription medicines via the website will be made after appropriate screening and advice provided by a pharmacist and in response to symptoms stated; all notes will be recorded on PMR.

3.90.2 Suitable advice given to patient and carers on how to manage illness via preferred method of communication (phone, text, email, video call).

3.90.3 The pharmacist will appropriately make sure the use of patients Summary Care Records after gaining patients consent to support patients if needed.

3.90.4 Signposting patients to the appropriate health care providers where/if necessary. Record of all signposting will be made on patients PMR.

3.90.5 Appropriate interventions made in accordance with the Promotion of Healthy Lifestyle.

3.90.6 Pharmacists will oversee all transactions and record all interactions on the patient's PMR. Therefore, if the pharmacist feels that the patient requires further assistance or that the condition is not in the category of self-care the patient can be signposted accordingly.

3.91 *Essential Services 7 – Clinical Governance - (**please refer to MS-SOP-V15.1 SOP for Clinical Governance**)*

3.92 "*Pharmacies have an identifiable clinical governance lead and apply clinical governance principles to the delivery of services. This will include use of standard operating procedures; recording, reporting and learning from adverse incidents; participation in continuing professional development and clinical audit; and assessing patient satisfaction.*"

3.93 The Superintendent Pharmacist will be the IG and CG Lead. They will be responsible to the regulators to deliver the required standards. They will be monitored and will audit their own and their staffs' performance against Key Performance Indicators. The pharmacy action plans will include their Clinical Governance 'SMART' objectives.

3.94 *Patient and Public Involvement*

3.94.1 A pharmacy leaflet will be available for all customers which will include the list of all NHS Services available. It will be displayed prominently on the Applicant's website.

3.94.2 Once trading, the pharmacy will produce a bi-annual patient satisfaction survey using the national template. The survey will be distributed to patients of the Applicant through the website and via the telephone and the post. The number of returned surveys will be assessed against the service specification. Results will be published on the web, shared with the relevant authorities and any outcomes from responses actioned appropriately.

3.94.3 The pharmacy will take complaints via the website, email, and telephone. The process will include recording the details and the Superintendent Pharmacist dealing with each complaint, considering the root cause, and signing off on each outcome and any agreed improvements to process to be implemented. All communication will be noted on the patients PMR for audit trail purposes and paperwork carried out for investigating the complaint, which will be filled out and filed securely on the pharmacy premises.

3.94.4 The outcome of all Patient and Public Involvement interactions, Forums and interactions with governing bodies will be re-assessed regularly against our own Quality Management System and Standard Operating Procedures.

3.95 *Clinical Audit*

3.95.1 The pharmacy will participate in regular audits to ensure the pharmacy and all processes and staff are compliant.

3.95.2 The outcomes of the audit, findings and any concerns/areas of improvement will be compiled into a report by the CG lead. This will then be reviewed with all staff at Medstone, fed back into the Quality Management System with the aim of further improving patient care.

3.96 *Risk Management*

3.96.1 Risk Management principles have been utilised within the creation of the Quality Management System.

3.96.2 Risk Management within the pharmacy will be monitored and assessed by the CG Lead.

3.96.3 All staff will be trained on the recording of incidents. Near miss logs will be carried out by all staff members, a patient safety review will be carried out every month. All near misses will be reviewed and risk assessments put in place to minimise errors.

3.96.4 Equipment maintenance on site will be recorded.

3.96.5 Clinical Governance training will be provided for all staff.

3.96.6 The Quality Management System for the pharmacy incorporates Standard Operating Procedures required for the running of the pharmacy. All staff will read and sign the SOPs Health and Safety documents as well as being provided with clinical governance training. If there are any changes/updates made to the SOPs then the superintendent will decide with staff, the need for formal training sessions or whether it is adequate for the staff to read and understand the updated SOPs and sign. It also incorporates Change Management, Risk Assessment and Training Protocols to comply with Clinical Governance protocols.

3.97 *Clinical Effectiveness Programs*

3.97.1 All staff will be trained according to their role and the patient interaction will be determined by the task, level of training, nature of the query and in accordance with the relevant Standard Operating Procedure.

3.97.2 All patients will be contacted by phone before a repeat prescription is ordered and/or dispensed to ensure there is a clinical need for the item to be dispensed. If necessary, the pharmacist may make a referral or contact the prescriber should there be any concern.

3.97.3 All staff will be trained to ensure the PMR will be maintained diligently to ensure all patient interactions are recorded and available for viewing by the relevant staff.

3.98 *Staffing and Staff Management*

3.98.1 All new staff will undergo a formal induction process and will be trained in all aspects of their role before commencing work in the pharmacy.

3.98.2 All new staff will need to read and sign the relevant SOPs to confirm their understanding of the process. Should any updates be made to the SOPs then the revised version will be submitted for circulation. In the instance of a major revision or change in regulations, the Superintendent Pharmacist may decide a formal training session needs to be scheduled.

3.98.3 There will be SOPs on whistleblowing policy for all staff members. (***Please refer to MS-SOP-V20.1 SOP for Risk Assessment and Whistleblowing***)

3.98.4 The Applicant will offer ongoing external training to all staff members as a means of continuing professional development.

3.98.5 All new staff will be required to produce their qualifications as well as being reference checked and id checked. Professional registrations may also be checked.

3.98.6 Any contractors used by the Applicant will be checked and copies of relevant SOPs requested.

3.98.7 The Applicant will comply with the Data Protection Act, all data and patient information will be kept secure, private and confidential.

3.98.8 All staff, locums and contractors will be aware of the data protection, General Data Protection Regulation (GDPR), confidentiality and NHS code of practice which will be part of the training modules and signed off to confirm their understanding.

3.98.9 The Applicant will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available upon request.

3.98.10 If data is breached; contact details will be available on who to report to. If there is an NHS data breach, then it must be immediately reported to NHS Digital Data Security Centre for immediate and further advice. Contact details will be available to all staff members. The incident must be reported as soon as possible within 72 hours if there is a breach of personal data. The Data Security and Protection Toolkit includes a tool for reporting data security incidents to the Information Commissioners Office, the Department of Health and Social Care and NHS England.

3.99 *Education, training and continuing professional and personal development*

3.99.1 All pharmacist and locums will be required to maintain CPD records and will be supported by the Applicant to do so.

3.99.2 Should any pharmacist wish to provide NHS Advanced or Enhanced Services the necessary training will be commissioned prior to commencement and SOPs followed. A GAP Analysis will be undertaken by the Superintendent Pharmacist in accordance.

3.100 *Use of information to support clinical governance and health care delivery*

3.100.1 The pharmacy will purchase the BNF, BNF for children and the Drug Tariff to support all pharmacy staff.

3.100.2 The website developers will produce with all legal obligations on data protection and confidentiality.

3.100.3 All staff and contractors will be aware of data protection, confidentiality and the NHS Code of Practice which will all be included within the training for all new staff members.

3.100.4 The PMR will be maintained and all interactions with patients will be recorded and documented. The pharmacist on duty will have the final professional say on all potential interventions.

3.100.5 A shredder will be used for all confidential waste, which then will be recycled.

3.100.6 Track and Trace Capability will be available on all deliveries to ensure traceability of all medicine orders that are dispensed by the pharmacy.

3.100.7 Any out-of-hours queries will be directed to NHS 111 via an automated phone message and clear instructions displayed on the pharmacy website. Patients requiring urgent assistance outside of hours will be directed to NHS 111 or their local A&E Department.

3.100.8 The opening hours of the pharmacy will be displayed on the website, on the phone service as well as on any leaflet or letter produced by the pharmacy that is sent to a patient.

3.101 *Essential Service 8 - Discharge medicine service - (**Please refer to MS-SOP-V021.1 SOP for NHS Discharge Medicine Service**)*

3.102 Discharge medicine service (DMS) referrals will be made to the pharmacy via secure electronic messages via PharmOutcomes, which will be set up at Medstone. A notification email will be sent to the pharmacy NHS email address which will be accessible by all staff members and will be checked at least 3 times a day. Referrals will be actioned within 72 hours of receipt by the responsible pharmacist. Consent will be taken by referring trust and patients will be able to withdraw consent in any stage. At the end of each month a report of standard dataset for each DMS provision will be submitted via MYS for payment.

3.103 STAGE 1 RECEIPT OF DISCHARGE REFERRAL

3.104 Patient details will be checked, medicines on discharge will be compared with admission via PMR and SCR. Any concerns will be raised with the NHS trust and patient GP. All notes will be added to the patients PMR. Alerts will be set up for stage 2 and 3 when the first prescription or contact is received. Any previous prescriptions that are not appropriate for supply will be returned to the spine or sent back via post to the surgery if sent non electronically.

3.105 STAGE 2 RECEIPT OF FIRST PRESCRIPTION FOLLOWING DISCHARGE

3.106 The pharmacist will compare the discharge referral with the post discharge prescription to ensure there are no discrepancies. If any discrepancies are found, then a referral will be made to the GP to resolve any issues identified. A record of this will be made on the patients PMR for audit trail. If consent is revoked after stage 1 or prescriptions are not received or contact cannot be made with the patient after a reasonable number of attempts, the GP will be notified and a note made on the patents PMR.

3.107 STAGE 3 SHARED DECISION MAKING DISCUSSION WITH PATIENT

3.108 The pharmacist will check the knowledge of the patient without face-to-face contact of what medication they are taking and if they are taking it correctly and safely. If the patient has any gaps in their knowledge or questions about their medication, the pharmacist will advise the patient accordingly. The conversation will be confidential and provided to the patient via a phone or video call in a confidential setting, like a consultation room. The patients' PMR will be updated with all the relevant notes and consent obtained from the patient. With patients consent, any valuable information that will benefit the patient will be shared with the GP to support their ongoing care. Patients will be offered the service for the return of any unwanted medicines per distant selling pharmacy regulations and an NMS service if applicable.

3.109 **Summary**

3.110 Pharmacy services are a growing demand where patients will always need medication and pharmacy services. The Applicant believes it can be an asset to the NHS providing patient centred care to patients in England safely and effectively.

3.111 The Applicant would therefore hope that [the Committee] has concluded that the team at Medstone are a reputable professional company who will conduct all NHS pharmacy services in a compliant and patient centric way. The Applicant endeavours to continually improve the range and quality of the services provided to their patients.

3.112 It is the Applicant's opinion that it has clearly demonstrated the ability of Medstone to operate a compliant distance selling contract through its application, appeal letter/supporting document and draft SOPs. Please refer to the Applicant's amended SOPs for more information/clarification.

3.113 The Applicant hopes that everything it has now submitted to NHS Resolution is satisfactory and that it has demonstrated it will follow NHS guidelines without breaching any rules, regulations or conditions. If NHS Resolution has any further questions, please don't hesitate to get in contact with the Applicant as it will be happy to supply any further information that may be needed to demonstrate its capability of running a distant selling pharmacy safely and effectively.

4 Summary of Representations

This is a summary of representations received on the Appeal.

4.1 THE ICB

4.1.1 Please note that from the 1 April 2023, community pharmacy contracting and commissioning has been delegated to integrated Care Boards (ICBs). Hertfordshire and West Essex ICB (HWE ICB) are hosting the function on behalf of the six East of England ICBs.

4.1.2 Please find below information the ICB wishes to be considered in relation to Medstone Ltd:

4.1.3 **RE: SHA/ 26052 - MEDSTONE LTD - APPLICATION FOR INCLUSION IN THE PHARMACEUTICAL LIST FOR A DISTANCE SELLING PHARMACY AT 110 BUTTERFIELD, INNOVATION CENTRE AND BUSINESS BASE, GREAT MARLINGS, LUTON, BEDFORDSHIRE LU2 8DL**

4.1.4 The Applicant is applying for inclusion to provide pharmaceutical services as a distance selling pharmacy under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations. The ICB would like to make the following observations.

4.1.5 Additional information has been provided in the appeal and the Applicant has provided a range of updated Standard Operating Procedures in order to demonstrate that all essential services will be provided safely and effectively, without face-to-face contact with anyone in England without any interruptions.

4.1.6 The ICB acknowledges that the Applicant has provided additional and missing information that was not available to the Pharmaceutical Services Regulations Committee (PSRC) at the time the decision was made.

4.1.7 The ICB notes that NHS Resolution will have regard to all information provided to date including the revised and additional information submitted by the appellant as part of this appeal.

5 Summary of Observations

No observations were received by NHS Resolution in response to the representations received on the Appeal.

6 Consideration

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

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").

Regulation 31

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. The Committee noted that the ICB had determined that it was not required to refuse the application under the provisions of Regulation 31 and no dispute had been raised on the matter by any other party. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

"(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

(2) The NHSCB must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(b) unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

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

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

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

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy the NHSCB in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.*

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

6.9.1 confirm the decision;

6.9.2 quash the decision and redetermine the application;

6.9.3 quash the decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter.

Regulation 25(1)

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

Regulation 25(2)(a)

6.11 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 Committee noted that the ICB had determined that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee noted that no other party had raised a dispute on the matter. 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)

6.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

6.13 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.

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

6.15 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 SOPs which the Applicant has prepared or commissioned.

6.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

6.17 The Committee noted in the information provided, the Applicant states that a responsible pharmacist (RP) will be on site at all times during the opening hours of the pharmacy. The Applicant further states that if the RP needs to leave the premises at any time, then a second pharmacist will sign in as RP and clearly display their RP notice. The Committee also had regard to ‘MS-SOP-V13.1’ the SOP for Role of Responsible Pharmacist.

6.18 The Committee noted the Applicant refers to the provision of services by telephone and email, with a website for patient use. The Applicant states that prescriptions would be received by the Electronic Prescription Service, fax and post. The Committee noted that the Applicant intends to use a delivery driver for deliveries within a 30 mile radius,

with Royal Mail being used outside this area. The Applicant also refers to the use of a controlled drugs courier and a cold chain courier for such items. The Committee noted the Applicant would telephone or video call patients after delivery to provide advice on correct usage. The Committee noted the SOPs refer throughout to contact with patients by telephone, email, and video call.

6.19 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.

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

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

Dispensing of drugs and appliances

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

6.23 The Committee noted that SOP 4 'Supply of Medicines' states under the heading "RECEIVING A PRESCRIPTION":

6.23.1 "*Prescriptions will arrive via post either directly from the prescriber or from the patient.*

Prescriptions will arrive electronically via the electronic prescribing service.

National prescriptions will all arrive by post occasionally preceded by a fax to allow for prior preparation.

Participating prescribers may have a collection service by a contract driver or may issue prescriptions to patients for posting to Medstone."

6.24 The Committee further noted that SOP 5 'Delivery of Medicines including controlled drugs and cold chain' states under the heading "HAND TO THE CONTRACT COURIER":

6.24.1 "*If the patient lives locally (up to 30-mile radius) then the pharmacy appointed delivery driver will be used, where there is no fridge lines or controlled drugs (CD) to be delivered. The driver will be appropriately trained on medication handling and an Enhanced DBS check will be carried out by the pharmacy prior to commencement of deliveries by the driver. All other deliveries will be delivered to the confirmed patient address via City Sprint and signed for by the patient or their representative. For the delivery of Controlled Drugs and cold chain medication these will be delivered by a suitability qualified MHRA approved courier, City Sprint Healthcare. This is a recognised and traceable courier in the case of cold chain, the temperature of the delivery can be traced when using 'pdq courier'. Patients will be notified via text, email or telephone of the tracking number of the delivery. All deliveries will require a signature upon delivery in order to confirm safe receipt of the medicines. In the event of a failed delivery due to the patient being away from home, an alternative date will be arranged.*"

6.25 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

6.26 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.

6.27 The Committee had regard to SOP 4 'Supply of Medicines' which, under the headings "EMERGENCY SUPPLY AT REQUEST OF PRESCRIBER" and "EMERGENCY SUPPLY AT REQUEST OF PATIENT", describes how the Applicant will process such a request. The Committee noted that the SOPs refer 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.

6.28 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

6.29 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.

6.30 The Committee noted that SOP 4 'Supply of Medicines' under the heading "RECEIVING A PRESCRIPTION" states:

6.30.1 "*Details of exemptions and proof where required would be requested.*

If exempt then ask patient to email proof of their exemption to our NHS email.

If they say they do not have proof but insist they are exempt then ask them which is their exemption and tick box accordingly along with evidence not seen at the back of the prescription.

If in any doubt about the validity of their exemption, then call the NHS and check.

Satisfactory evidence includes evidence derived from a check, known as a real time exemption check, of electronic records that are managed by the NHSBSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under the Charges Regulations.

Evidence of exemption can be sent to the pharmacy via the pharmacy delivery driver which can be returned to the patient.

The patients' records should be updated with the exemption and the expiry date should be added. For income-based exemptions, patients should be asked to provide evidence on each occasion to ensure their continued entitlement.

The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. For deliveries made by drivers other than the pharmacy driver, patients can email/fax a copy of the exemption to the pharmacy. Pharmacy staff can note that the exemption was not seen in the original format.

The RP can determine whether the evidence provided is satisfactory. For patients using the postal service to post evidence of their exemption status, advise the patient to use Special Delivery services or the pharmacy's courier service. The pharmacy should cover the cost and return the exemption to the patient using the same method.

The reverse of the prescription should be fully completed (other than age exempt patients) in black ink."

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

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

6.33 The Committee further noted that SOP 4 'Supply of Medicines' under the heading "RECEIVING A PRESCRIPTION" states:

6.33.1 "*If not exempt, then the patient would be advised about payment methods:*

Check the prescription to confirm how many charges are due.

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the 'customer not present' option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

6.34 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

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

6.36 The Committee considered the information before it contained in the SOPs as submitted by the Applicant.

6.37 The Committee noted SOP 5 'Delivery of Medicines including controlled drugs and cold chain" under the heading "PREPARATION" states:

6.37.1 "*1. Before making a delivery, the patient would be contacted to arrange a suitable delivery date and agree an approximate delivery time.*

For a CD delivery, the patient or representative will be informed that they have to provide ID. Representative ID would be kept on file in advance, and every time a delivery is made to the representative, the patient would be consulted to confirm this is still correct.

2. Ensure that prescriptions intended for delivery are appropriately bagged, boxed and labelled (explained in detail further down).

If to be delivered to a pre-determined patient representative the correct details must be added to the despatch information. Patient to be advised that nominated representative must be able to produce valid ID and be over 16 years of age.

3. Complete the contract courier dispatch paperwork and online requirements with the:

Patient details: name and address

Ensure any special requirements or messages for the patient or representative are highlighted e.g. Storage of medication if it is a fridge item/CD or information to patient

Ensure that if the medication is to be delivered to a third party (e.g. a patient's representative) that the delivery sheet includes their address

If the prescription is to be delivered to a patient's representative, the patient must have specifically authorised the pharmacist to deliver to the third party in advance of the delivery being made."

6.38 The Committee noted that the SOP went on to state under the heading "HAND TO THE CONTRACT COURIER":

6.38.1 "1. *Ask the delivery driver to check the details on their delivery sheet to determine if any necessary information is missing (such as postcodes).*

2. Ensure that any deliveries for fridge and CDs are taken out of storage just in time for pick-up.

3. Ensure that the delivery driver is notified of any messages for the patient i.e. to contact the pharmacy direct with any queries or for product information.

4. Ensure driver checks delivery items including fridge items and CD against delivery sheet prior to leaving the pharmacy.

5. Obtain and keep a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day. Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. Ensure the delivery vehicle is always locked when left unattended.

6. Once dispatched, the patient would receive an email to state that the delivery has left the pharmacy and that it is on its way to the patient. All deliveries will be tracked by City Sprint in accordance with their SOPs.

7. All CD deliveries carried out by City Sprint will be carried out in accordance with their CD SOPs and in line with the Medicines Act.

8. All cold chain deliveries will be delivered by City Sprint couriers. City Sprint cold chain services include temperature-controlled packaging for transit ensuring temperatures are maintained between 2-8 °C. Temperature monitoring is carried out throughout the delivery. Once cold chain medication is ready and delivery date has been confirmed with patient, City Sprint will be contacted to deliver cold chain medication safely and directly to the patient. Paperwork of this will be secured safely in the pharmacy. The cold chain item should be kept in the fridge until the courier arrives to accept the delivery. Confirm with the courier that the delivery will be maintained at the booked temperature range and ask for real time temperature log to ensure the cold chain medication isn't breached. The pharmacy will select a delivery

maintaining 2 – 8°C unless the item requires shipping at a different temperature. City Sprint will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved. This is a dedicated, fully monitored and temperature-controlled delivery service. Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach. The pharmacy will ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

The cold chain item should be kept in the fridge until the courier arrives to accept the delivery. Confirm with the courier that the delivery will be maintained at the booked temperature range and ask for real time temperature log to ensure the cold chain medication isn't breached. Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach. The pharmacy will ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

9. For CDs and Fridge Lines the pharmacy will ring the patient shortly after expected delivery time to confirm safe receipt and to validate the tracking information.

***RP must be available to supervise the handing over of all delivery items. ***"

6.39 The Committee noted the SOP goes on to state:

6.39.1 "*DELIVERY OF PRESCRIPTION*

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

2. City Sprint drivers will be trained in all the appropriate procedures required to deliver medicines. Controlled Drug procedures require a zero tolerance policy.

Check the name and address against the delivery records and packaging labels.

Ask the patient or representative for their name, address and signature as proof of delivery in accordance with City Sprint SOPs. Where required, request proof of ID.

Ask the patient or representative to sign for their delivery.

Pharmacist should contact any patients for whom there are relevant messages or counselling required.

3. If they are unable to sign (in exceptional circumstances), the driver will hand the medication to the patient or representative, and write a note on the delivery sheet with the medical reason why they are unable to sign. In this instance, the driver will need to inform the Pharmacist.

4. 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 the parcel due to its nature or make arrangements to have it left with a neighbour. They are offered the option to have it delivered to an alternative address such as their office or work place if appropriate.

SUCCESSFUL DELIVERY

1. Confirmation of delivery would be received from the courier service via them faxing the completed delivery sheets and if required, the controlled drug record sheet, to the pharmacy. All deliveries can be tracked via the courier service from the pharmacy.

2. For CDs and Fridge Lines the pharmacy will ring the patient shortly after delivery time to confirm safe receipt and to validate the tracking information.

3. The pharmacist must maintain an audit trail and has a responsibility to make sure the CD was delivered accurately. The City Sprint driver should report back to the Pharmacist with a completed delivery sheet/or signed for document.

4. Entry must be entered in to the CD register when the CD leaves the pharmacy premises and enter the pharmacy courier as the 'person collecting' – this is a legal requirement and should be completed in a timely manner. Retain the prescription in the pharmacy until the pharmacy driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online when delivered by approved courier. If controlled drugs are being sent, then the City Sprint driver must be informed when carrying controlled drugs and ensure the secure transportation.

5. Delivery of controlled drugs (CDs) can be made to the patients, or their representations PROVIDED the patients have given written authorisation for their representatives to take the CDs on their behalf.

6. CDs and any other medicines on that patient's delivery must be stored in a lockable compartment of the delivery vehicle and out of sight. The delivery vehicle must be kept locked and secured at all times when it is unattended.

UNSUCCESSFUL DELIVERY

1. If the patient or representative is not able to receive the delivery of their medication, the driver must log this within their tracking system and contact the pharmacy for further instructions.

2. The driver WILL NOT:

Post the medication through the letter/post box or leave unattended

Leave the medication on the porch or in any other building

Leave at an unauthorised address

3. Fridge Line stock will be stored in City Sprint safe overnight storage facility. The pharmacy will be contacted to arrange alternate delivery date to customer.

4. If the delivery cannot be made then the CDs must be returned to the pharmacy the same day. If this is not possible due to the time of day or location of the patient, then the CDs must be taken back to the City Sprint CD safe storage location and will await further instruction from the pharmacy.

5. In the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact. In the event of such an occurrence, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. Items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock.

Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight. When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy."

6.40 The Committee noted that SOP 7 'Ordering of Controlled Drugs', SOP 8 'Dispensing and Record Keeping Controlled Drugs' and SOP 9 'Controlled Drugs Stock Balance Checks' detail how the Applicant will monitor, audit and keep secure Controlled Drugs.

6.41 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.

6.42 The Committee noted that the application form had indicated that the Applicant wished to supply the following items:

6.42.1 Dressings

6.42.2 Hosiery and compression bandages

6.42.3 Catheter appliances

6.42.4 Incontinence appliances including sheaths and catheter bags

6.42.5 Stoma appliances

6.43 On appeal the Applicant has indicated that it does not intend to provide appliances which require measuring or fitting. The Committee noted that on receipt of such requests, the Applicant would contact the patient and signpost them to at least two other providers of the service in their area.

6.44 In the event that the application is granted and on the basis of 6.43, the Applicant would not therefore, be able to provide such appliances to patients.

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

6.46 The Committee noted that SOP 5 'Supply of Medicines' further states:

6.46.1 "*Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.*

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

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

Medicine (excluding CD and fridge lines) for local delivery (up to 30 miles) which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items. Padded envelopes can be used as well to ensure the integrity of the manufacturers packaging.

Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leakproof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids).

Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage. For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type. Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.

…

Cold chain items should be bubble wrapped and stored in Styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers.

Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored ("cold ship" packaging).

Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them…."

6.47 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 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

6.49 The Committee noted that SOP 10 'Repeat Dispensing' states under the heading "PHARMACEUTICAL & LEGAL ASSESSMENT":

6.49.1 "*7. Check whether the RA form states a dispensing interval and that the medicine is due.*

- If the RA form does not state a dispensing interval, then the pharmacist should use their professional judgement when to

dispense the next supply for the patient. They must be satisfied that the supply of medicines is clinically appropriate.

8. Pharmacist should contact patient via telephone/video call and ensure:

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

- They are not suffering any side effects which may suggest they need a review of their medication.

- Their medication regimen has not been changed since the prescriber authorised the repeatable medication.

- There have not been any changes to the patient's health since prescription was authorised.

- If the patient requires the full quantity of all medicines or do they have a surplus of stock at home already (thus reducing medicine wastage)

9. Medicines will only be supplied where the pharmacist is satisfied that the patient is taking and is likely to continue to take the drug appropriately and is not suffering from any side effects which indicate the need or desirability to review the patient's treatment.

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

11. Make a note of whether the patient requires all the medicines on the prescription or if they require a part supply."

6.50 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

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

6.52 The Committee noted that SOP 10 'Repeat Dispensing' states under the heading "PRESCRIPTION RECEPTION":

6.52.1 "*1. For patients new to the NHS repeat prescription service:*

- Contact the patient by telephone and explain the service and the benefits, such as not having to contact the surgery at regular intervals to request medication and minimal wastage of medication etc.

- Ensure the patient completely understands the service.

- Ask patient to fill in consent form online or send consent form out via post with prepaid envelope if patient does not have access to the web.

- Ask the patient whether they would like to keep their 'Repeat Dispensing (RD)' forms or whether they wish the pharmacy to retain them. If the patient wants to keep them then retain the 'Repeat Authorisation (RA)' copy in the pharmacy and send all remaining RD forms (with prepaid envelopes) to patient with their medicines. Inform patient that they must post relevant RD forms to the pharmacy in advance of the due date. If they wish the pharmacy to retain all the forms explain to patient that they must inform pharmacy either via e-mail or telephone when they wish us to dispense their medicine.

- Provide patient with any additional information required to support their ongoing treatment and to affect positive outcomes and minimise wastage."

6.53 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

6.54 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.

6.55 The Committee had regard to SOP 6 'Disposal of Medicines' which states under the heading "PROCEDURE":

6.55.1 "*1. The Responsible Pharmacist or Superintendent Pharmacist will authorise staff to be deemed competent to be able to dispose of medicines within the pharmacy.*

2. They will also ensure that patients who have returns and need them picked up will be sent returns paperwork to ensure a safe collection and return to the pharmacy by the chosen courier, Stericycle (SRCL), who are well established compliance company in collecting and disposing of medical waste.

3. The returns paperwork will include a label "For Disposal not For Resale" The patient will be asked to pack the returns safely in the packaging sent to them and stick on the returns labels sent to them.

4. They will be asked to contact the pharmacy with a suitable time for the returns to be collected and then arrangements will be made with the courier.

5. The customer will be asked to list the medication to be returned so that the pharmacy can advise the waste collection company.

6. An account will be set up with SCRL to provide this service and Direct365 to ensure the correct bins are supplied to the pharmacy for medicine waste disposal.

7. Medstone will ensure to obtain an upper tier waste disposal license as an extra service that can be offered.

8. Any person returning unused/unwanted medicines via waste disposal services should be asked by the staff to ensure there are no sharps to be returned. i.e., needles, injections, pens with needles.

9. Patients will be signposted to local services to arrange for sharps collection and they will be asked if they are aware of how to safely dispose of their medication.

10. An additional label will be attached to every pharmacy delivery to remind patients not to hoard out of date or unwanted medicines and to return them to their nearest pharmacy if this is not possible, they should contact Medstone and they will arrange a pickup as detailed above.

11. Check the medication for any cytotoxic or hazardous waste. Confirm with pharmacist if required.

12. Check for any flammable items and segregate these items until removed by the waste contractor.

13. Controlled Drugs (schedule 2 and 3) will be made irretrievable and steps will be put in place to make a record of the disposal, with respect to safe custody regulations. The pharmacy will collect unwanted and out of date-controlled drugs from patients' homes via City Sprint Healthcare for tracked secure medication returned to the pharmacy.

14. Where patients are returning a large quantity of the same medication, then the pharmacist should be made aware of this in case of a compliance issue.

15. Returned medication should not be visible and must be stored in the quarantined area of the vehicle for return to the pharmacy for destruction."

6.56 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

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

6.58 The Committee noted SOP 14 'Promotion of Healthy Lifestyle' states:

6.58.1 *"The pro-active participation in national/local campaigns, to promote public health messages to pharmacy users during targeted campaign periods.";* and

6.58.2 *"The website will also be used to promote healthy lifestyles.*"

6.59 The Committee further noted that the Applicant states in the letter of Appeal that:

6.59.1 "*The Applicant's website which will include general health information as well as information regarding specific public health campaigns, where there will be an interactive page clearly promoting to any person to access the website.*"; and

6.59.2 "*The website will have up to date materials that promote healthy lifestyles by addressing reasonable* [sic] *range of health issues such as diabetes, heart disease, blood pressure etc.*"

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

Prescription linked intervention

6.61 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.

6.62 The Committee noted SOP 14 'Promotion of Healthy Lifestyle' states:

6.63 "*Identification of patients takes place through three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process:*

6.63.1 *Active patients are those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information.*

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

6.63.3 *All patients who have prescriptions dispensed or purchase medicines from the pharmacy need to fill in the Lifestyle Questionnaire which asks for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.*

6.63.4 *Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them.*

6.63.5 *The website will also be used to promote healthy lifestyles.*"

6.64 The Committee noted further that the SOP states under the heading "PRESCRIPTION LINKED INTERVENTION":

6.64.1 "*Opportunistic advice is expected to be given on specified healthy living / public health topics to the following group of patients who have their prescriptions fulfilled by the pharmacy.*

In particular, for patients with:

- diabetes

- coronary heart disease

- high blood pressure

- smokers

- obesity/overweight

Dispensary staff members can identify these patients:

- through the type of medication being requested

- the online questionnaire completed by all new patients - Patients can be sent the questionnaire which can be returned via post (with prepaid envelope).

- the patient's PMR and order history

- via any communication – phone, email, live chat or video link. Newsletters shall be sent out/emailed to patients as well

2.

- via communication from the initial prescriber.

3. Further to this, patients can be identified as part of the repeat dispensing service or through other interactions such as a sale of a medication.

All these reference points will assist dispensary staff to facilitate the discussion.

4. Advice can be given verbally over the phone, via email contact as well as an insertion of leaflets within the prescription that is delivered to the patient. Advice may also include referral to another source of advice or assistance and may include other health professionals.

5. Once a prescription-linked intervention has been made, a note will be made on the PMR by the appropriate staff member. This note will ensure continuity of advice and as a reference for future interactions with the patient."

6.65 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

6.66 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 NHS England.

6.67 The Committee noted that SOP 14 'Promotion of Healthy Lifestyle' states under the heading "CAMPAIGN BASED SERVICE":

6.67.1 "1*. Medstone will pro-actively take part in and contribute to national/local campaigns for all patients registered to their website.*

Throughout the campaign period, advice will be provided to all patients in the form of a newsletter via their preferred mode of communication as specified in their patient questionnaire.

Advice can also be given via general phone/email communications and printed/email leaflets will be available for distribution.

The pharmacy website will have a specific area for health campaigns. This will allow outbound links to accredited organisations and clear routes to further resources and, if applicable, help or resource engagement.

The pharmacy website will have a HTML5 banner on the home page promoting local and national campaigns; each promotion topic will have a link through to the relevant web page as mentioned in the previous paragraph.

Patients can speak to the pharmacist throughout the opening hours, ensuring the uninterrupted provision of services to patients across England. Patients can

always access information on the website. Website links should be updated for each campaign. During a campaign, relevant patients who may benefit from further information should be identified. A note should be made on the patients record to show they have received information as part of the campaign. Records of advice given via phone/video consultation should be made to help facilitate service audit, help with future follow ups with the patient and also to distinguish the number of patients who have taken part in the campaign.

2. The pharmacy will contribute in campaigns as directed by NHS England and Public Health England. Other campaigns may be as advised by the Local Area Team/Health and Wellbeing Board.

3. Each year the pharmacy is required to participate in up to 6 health campaigns at the request of NHS England. Medstone will pro-actively take part in national health campaigns/ community engagement to promote public health messages to patients. Leaflets should be sent out to patients along with their prescriptions during specific target campaign periods. Information will be provided non face to face on the website and relevant links will be provided to patients via text and email. This will ensure that patients are able to always access information about health campaigns. Throughout the campaigns, Medstone will maintain a record of the number of people who receive the advice to ensure traceability. In addition, a review of the effectiveness of the campaign will be undertaken where possible and outcomes recorded."

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

Signposting

6.69 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.

6.70 The Committee noted that the SOP 'Safeguarding and Signposting' states under the heading "SIGNPOSTING PROCEDURE":

6.70.1 "*This procedure will ensure that patients of Medstone can access further care and support appropriate to their needs.*

o Any referral made should be added to the PMR including a record of the advice.

o References to access appropriate health care providers can be relevant Health and Wellbeing Boards, Local Area Teams and NHS Choices (www.nhs.uk).

o Our website will contain information that will signpost patients to healthcare pages such as NHS choices if they require more information regarding a certain ailment.

o Our website will provide a list of useful contacts for out-of-hours advice on a national level.

o Our website will urge patients to ring during core opening hours so the pharmacist can make an assessment and signpost the patient more effectively.

o If patients contact the pharmacy via phone outside the core opening hours or when the pharmacy is closed, they will be given an option to leave a message for the pharmacist for non-urgent matters and

encouraged to use the 111 service if the situation cannot wait for the pharmacy to open, or if life threatening or extremely urgent to call 999

o Video calls via Skype, Zoom, WhatsApp will be available for consultations whereby a visual of the symptoms may be necessary.

o The pharmacy will utilise NHS choices as a directory of health and support.

o Patients can be identified for signposting through any interaction taken place between staff and patients. Results from the healthy lives questionnaire used in the 'Promotion of Health Lifestyles' survey can also be used.

o The responsible pharmacist will complete a communication sheet with all patients and will be trained to make signposting recommendations. All details will be recorded on the PMR.

o CPD training will be undergone by all pharmacists to enable effective signposting."

6.71 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

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

6.73 The Committee noted that SOP 18 'Support for Self-Care' states under the heading "PROCEDURE":

6.73.1 "*o Suitable advice will be given to patients and carers on how to manage illness by phone or video link.*

o Patients will be signposted to appropriate health care providers when necessary. Where the patient is identified to require support or advice that the pharmacy staff are unable to provide or services like measuring and fitting, then the patient should be signposted to a suitable provider of health and social care, pharmacy who is able to provide the support and service required. The pharmacy will provide the patient with contact details of at least two suitable providers.

o Appropriate interventions will be made in accordance with the Promotion of Healthy Lifestyle (see MS-SOP-V14.1.) The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues. The health promotion zone may also include details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."

6.74 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

6.75 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.

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

6.77 The Committee noted that in the letter of appeal the Applicant states:

6.77.1 "*Discharge medicine service (DMS) referrals will be made to the pharmacy via secure electronic messages via PharmOutcomes, which will be set up at Medstone. A notification email will be sent to the pharmacy NHS email address which will be accessible by all staff members and will be checked at least 3 times a day. Referrals will be actioned within 72 hours of receipt by the responsible pharmacist. Consent will be taken by referring trust and patients will be able to withdraw consent in any stage. At the end of each month a report of standard dataset for each DMS provision will be submitted via MYS for payment.*

6.77.2 *STAGE 1 RECEIPT OF DISCHARGE REFERRAL*

6.77.3 *Patient details will be checked, medicines on discharge will be compared with admission via PMR and SCR. Any concerns will be raised with the NHS trust and patient GP. All notes will be added to the patients PMR. Alerts will be set up for stage 2 and 3 when the first prescription or contact is received. Any previous prescriptions that are not appropriate for supply will be returned to the spine or sent back via post to the surgery if sent non electronically.*

6.77.4 *STAGE 2 RECEIPT OF FIRST PRESCRIPTION FOLLOWING DISCHARGE*

6.77.5 *The pharmacist will compare the discharge referral with the post discharge prescription to ensure there are no discrepancies. If any discrepancies are found, then a referral will be made to the GP to resolve any issues identified. A record of this will be made on the patients PMR for audit trail. If consent is revoked after stage 1 or prescriptions are not received or contact cannot be made with the patient after a reasonable number of attempts, the GP will be notified and a note made on the patents PMR.*

6.77.6 *STAGE 3 SHARED DECISION MAKING DISCUSSION WITH PATIENT*

6.77.7 *The pharmacist will check the knowledge of the patient without face-to-face contact of what medication they are taking and if they are taking it correctly and safely. If the patient has any gaps in their knowledge or questions about their medication, the pharmacist will advise the patient accordingly. The conversation will be confidential and provided to the patient via a phone or video call in a confidential setting, like a consultation room. The patients' PMR will be updated with all the relevant notes and consent obtained from the patient. With patients consent, any valuable information that will benefit the patient will be shared with the GP to support their ongoing care. Patients will be offered the service for the return of any unwanted medicines per distant selling pharmacy regulations and an NMS service if applicable*."

6.78 The Committee also had regard to SOP 21 'NHS Discharge Medicine Service' which outlines further details regarding the procedure for each stage of the process.

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

Websites and health promotion zones

6.80 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.

6.81 The Committee noted that in its letter of Appeal the Applicant states:

6.81.1 "*The Applicant's website which will include general health information as well as information regarding specific public health campaigns, where there will be an interactive page clearly promoting to any person to access the website.*

6.81.2 *The website will have up to date materials that promote healthy lifestyles by addressing reasonable* [sic] *range of health issues such as diabetes, heart disease, blood pressure etc.*"

6.82 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

6.83 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

6.84 Given that further information, including the Applicant's SOPs, was provided by the Applicant with its Appeal which had not been seen by the ICB when considering the application, the Committee determined that the decision of the ICB must be quashed.

6.85 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the ICB) or whether it was preferable for the Committee to reconsider the application.

6.86 The Committee noted that representations on Regulation 25 had already been made by parties to the ICB, and these had been circulated and seen by all parties as part of the processing of the application by the ICB. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the ICB; and

7.2.2 redetermines the application as follows -

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

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

7.2.2.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours,

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

7.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner,

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

7.2.3 The application is granted.

Case Manager
Primary Care Appeals