

20 April 2023

REF: SHA/25842

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APPEAL AGAINST NHS ENGLAND (NORTH EAST AND YORKSHIRE AREA TEAM) DECISION TO REFUSE AN APPLICATION BY MEDIVAL (YORKSHIRE) LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 100 ALLERTON ROAD, BRADFORD, BD8 0AZ UNDER REGULATION 25

1 Outcome

- 1.1 The Pharmacy Appeals Committee (“Committee”), appointed by NHS Resolution, quashes the decision of NHS England and redetermines the application.
- 1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Medival (Yorkshire) Ltd
Community Pharmacy West Yorkshire (the LPC)
PCSE on behalf of NHS England – North East and Yorkshire Area Team

Advise / Resolve / Learn

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1 The Application

By application dated 9 December 2021, Medival (Yorkshire) Ltd (“the Applicant”) applied to NHS England for inclusion in the pharmaceutical list at 100 Allerton Road, Bradford, BD8 0AZ 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 left this part of the application form blank.
- 1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this part of the application form blank.
- 1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left this part of the application form blank.

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

- 1.4 Please find below information to explain how the pharmacy procedures used within the premises will secure:
 - (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.
- 1.5 The premises will be safe and secure and will include telephone, internet connection and provide delivery services. A pharmacist shall be present throughout all core opening hours to supervise every transaction involving pharmacy or prescription only medications. Dispensing of any drug or appliance shall be done under the supervision of a pharmacist. The premises shall provide all medications when a prescription is received. All types of NHS prescriptions shall be dispensed with reasonable promptness. When delivering high risk and low risk medications varying degrees of photo ID verification shall be carried out. Essential services shall not be provided to persons present at or in the vicinity of the premises. If an appliance which requires measuring and fitting is being provided, this activity shall be completed by a pharmacist outside of the premises. If any advanced or enhanced services are provided face to face, there shall be no overlap with an essential service because of the attendance of a patient at the premises.

- 1.6 If a patient attends the premises asking for any of the essential services, they will be advised that this premise does not provide essential services face to face. Essential services are provided ONLY online or via telephone and he/she should contact the premises via this method. They would also be advised that, as an alternative they can go to another "brick and mortar" pharmacy for face-to-face essential services.
- 1.7 Any advanced services shall be provided on a pre-arranged appointment basis. When making the appointment, the patient shall be clearly informed that when he/she attends his/her appointment, there shall be no essential services provided and the appointment is offered only on this basis. Appropriate SOPs shall be in place and all members of staff shall be trained and made aware of the procedures to ensure the above is adhered to.

2 The Decision

NHS England considered and decided to refuse the application. The decision letter dated 22 December 2022 states:

- 2.1 NHS England has considered the above application and is writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

Extract from the report

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

- 2.2 The Pharmaceutical Services Regulations Committee (hereafter referred to as "the Committee") considers all pharmaceutical services applications on behalf of NHS England & NHS Improvement East of England in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as "the Regulations").
- 2.3 The Committee has now considered your application and is writing to confirm that it has been rejected.
- 2.4 This application was considered under Regulation 25(2)(a) & (b), Regulation 31 and Regulation 64 -which sets out the specific conditions to be met by applications for Distance Selling Premises.
- 2.5 The Committee considered Regulation 31 and agreed that this does not apply as there is no pharmacy at the same or adjacent premises to the proposed site.
- 2.6 The Committee then considered Regulation 25 and determined that it had not been met.
 - 2.6.1 Regulation 25(2)(a) it was confirmed this was not applicable as no primary care provider with a patient list is present within the same premises as the proposed site.
 - 2.6.2 Regulation 25(2)(b) is not met as the applicant has not demonstrated how services will be provided remotely, and without interruption throughout the given opening hours.
- 2.7 Regulation 64 - Regulation 64 sets out the specific conditions to be met by applications for Distance Selling Premises:
 - 2.7.1 The applicant must not offer to provide pharmaceutical services, other than directed services, to persons who are present or in the vicinity of the pharmacy premises.

- 2.7.2 The means by which persons receive services from the pharmacy must be otherwise than at the pharmacy premises.
 - 2.7.3 The pharmacy premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.
 - 2.7.4 The pharmacy procedures must ensure the uninterrupted provision of essential services, during the pharmacy opening hours, to persons anywhere in England who request the services and must ensure the safe and effective provision of essential services without face-to-face contact between the person receiving the services and the pharmacy staff.
 - 2.7.5 The pharmacy must not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.
- 2.8 Following consideration of the information provided by the Applicant in the application form, the additional information supplied, the representations and the applicants response to the comments in the representations, the Committee rejected the application. The Committee noted that the Applicant had provided limited information within the application form and that whilst the Applicant had addressed each of the respondents comments providing additional information, the information provided still did not satisfactorily provide assurance that the specific conditions set out in Regulation 64 would be met in providing safe and effective essential services.
- 2.9 NHS England therefore rejected the application for Distance Selling Premises on the grounds that the Applicant had not met the requirements set out in Regulation 25 and Regulation 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- 2.10 Appeal rights are granted to:
- 2.10.1 The Applicant

3 **The Appeal**

Under cover of an email of 20 January 2023 and using the “On line form for pharmacy application appeals” dated 19 January 2023, the Applicant appealed against NHS England’s decision. The grounds of appeal are:

- 3.1 Please find below further information explaining how the pharmacy procedures (SOPs) used within the premises will secure the following:
 - (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.
- 3.2 The responsible pharmacist (RP) shall remain in the pharmacy during the entire proposed opening hours in accordance with RP regulations as detailed by GPhC.
- 3.3 The RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless another pharmacist is present.

- 3.4 There will be a second pharmacist available during the core and any additional hours that the pharmacy operates. If the RP is required to leave the premises or takes a break (as per Working Time Directive) then the second pharmacist will assume responsibilities as the RP.
- 3.5 Patients from anywhere in England may contact the pharmacy to request NHS Essential Services by phone, email, website, fax and writing during the entire proposed opening hours, without face to face contact. The website will be accessible 24 hours a day throughout the year.
- 3.6 All NHS Essential Services shall be delivered in a safe and effective manner in accordance with the attached pharmacy SOPs:
- 3.6.1 To persons anywhere in England who request these services, during the opening hours of the premises, without interruption.
- 3.6.2 Without face to face contact between the patient or their representative and the Pharmacy owner or their staff.
- 3.7 In addition, the pharmacy shall comply with Regulation 64 as follows: -
- 3.7.1 The Pharmacy shall not provide any services other than directed services to persons who are present or in the vicinity of the pharmacy premises.
- 3.7.2 Patients receiving services, other than directed services, from the pharmacy must be by means other than at the pharmacy premises.
- 3.7.3 The pharmacy premises is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.
- 3.7.4 The pharmacy will not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the NHS essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.
- 3.8 The pharmacy premises shall be designed to ensure safe and effective workflow for dispensing.
- 3.9 All staff within the pharmacy will be trained to deliver pharmacy services, including Continued Professional Development (CPD) where appropriate. In addition, all staff shall adhere to legislation, procedures and guidance as set out in the pharmacy standard operating procedures.
- NHS Essential services shall not be provided to patients or their representatives on or near the proposed site.
- Any person requesting essential services anywhere in England shall be delivered any of the essential services without face-to-face contact whether on their own or someone else's behalf.
- 3.10 Listed below are concise and reasoned statements highlighting provisions made to ensure all essential services are delivered to anyone in England without any face to face contact safely and effectively upon request.

Discharge Medicines Service

- 3.11 Discharge Medicines Service shall be provided to all referred patients. All three stages of the Discharge Medicines Service shall be provided without face to face contact through suitable means of communication. The pharmacist will use their clinical judgement, when considering their actions/recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussion about the patient and their medication. For further details see attached document ref MYL-005.

Dispensing Medicines

- 3.12 Prescriptions can be received by the pharmacy via EPS 2, post, collection from GP surgery with consent and via fax. Dispensed prescriptions will be delivered directly to patient's home/address (including controlled drugs and fridge lines) using a variety of secure and confidential methods such as own delivery staff, courier and appropriate royal mail service.
- 3.13 In the case of Controlled Drugs couriers/drivers shall be informed that they are carrying a CD to ensure secure transport in accordance with guidance i.e. secure containers.
- 3.14 For fridge lines courier/drivers shall be informed that cold chains shall be maintained by the use of appropriate containers and where appropriate will ensure an auditable cold chain in line with SOP's.
- 3.15 All deliveries containing Controlled Drugs and fridge lines shall be tracked through transit. In case the pharmacy is employing a company to do the delivery, sufficient auditing processes shall be put in place to ensure all medication can be tracked at any point in transit.
- 3.16 In the event of exemption status not being signed by the patient/representative, pharmacy staff must confirm exemption via telephone, email, and sign accordingly. NHS charges payments may be collected electronically or over the phone or via driver/courier.

Repeat Dispensing

- 3.17 Process for repeat prescription is as detailed above for dispensing (where applicable). For further details refer to document MYL-011.
- 3.18 In addition, appropriate advice about the benefits of repeat dispensing shall be given to patients who:
- 3.18.1 have long term stable medical conditions
 - 3.18.2 require regular medication in respect of their medical condition including where appropriate advice that encourages the patient to discuss repeat dispensing of that medicine with the prescriber
- 3.19 Advise [sic] shall be given using permissible forms of non-face to face contact with patients.

Disposal of Unwanted Medicines

- 3.20 Patients wishing to return unwanted medication to the pharmacy will be able to do so by pharmacy own driver/courier which will be provided and paid for by the pharmacy.
- 3.21 Appropriate packaging will be sent to patients and details of the service and how to book a collection will be available on the pharmacy website.

- 3.22 Upon return to the pharmacy, unwanted medicine shall be sorted and placed in disposal units ready for specialist waste management company to collect. For more details refer to MYL-005.

Promotion of healthy lifestyles & Public Health Campaigns

- 3.23 All patients will be asked to fill out a healthy lifestyle questionnaire which can be returned via post or can be completed on the pharmacy website. On receipt of the completed questionnaires pharmacy staff can use the results to identify and select patients who can be contacted and provided with additional information and support.
- 3.24 Patients can also be identified through dispensing of prescriptions or as part of the repeat dispensing process. Patients can be given specific material regarding their conditions. Details of health and social care providers and local support groups can be given to patients via telephone, email, website etc.
- 3.25 Patients can be identified to have medical conditions from their prescriptions or through other interactions such as a sale of a medication. Suitable advice should be given to any patients who would benefit from support for self-care. Leaflets and newsletters shall be delivered along with their medication as well as targeted campaigns. The pharmacy website shall also be used to promote healthy lifestyles.
- 3.26 The pharmacy will pro-actively take part in national health campaigns/community engagements 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.
- 3.27 For further details refer to document MYL-024.

Support for self-care, Signposting & Health Promotions

- 3.28 Where the patient is identified to require support or advice that the pharmacy staff are unable to provide, then the patient should be signposted to a suitable provider of health and social care who is able to provide the support required. Provide the patient with contact details of at least two suitable providers if possible.
- 3.29 For further details refer to document MYL-022

Clinical governance

- 3.30 According to service specification. Patient contact will be achieved via non face-to-face methods etc. telephone/email/text.
- 3.31 The Pharmacy is committed to meeting the clinical governance requirements as laid out by the National Health Service (Pharmaceutical Services) Regulations. The pharmacy will be compliant with all components of clinical governance which includes, but is not limited to standard operating procedures, patient survey's, conducting audits, patient safety incident near miss reporting and keeping the pharmacy practice leaflet up to date.

Standard Operating Procedures

- 3.32 The pharmacy has employed a consultant to develop a suite of operating procedures that cover the operation of the distance selling contract. The Applicant has not provided all of the SOPs with this appeal however, if NHS England [sic] requires any further information about any aspects of the operation of the pharmacy then the relevant SOPs will be provided, upon request.

- 3.33 The Applicant notes that clauses 27 and 28 of NHS England’s National Policy Document Number: OPS_1005, “Policy for monitoring compliance with the terms of service for pharmacy and dispensing appliance contractors” states in the SOP section that:

“The essential service and clinical governance specifications require pharmacies to have appropriate standard operating procedures for dispensing, repeat dispensing and support for self-care. Monitoring compliance requires only the determination of whether the pharmacy has an appropriate SOP. It does not require NHS England to carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for an NHS England employee to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned. Any shortcomings not identified, or suggestions made which themselves cause problems in delivery of the services could lead to NHS England itself being involved in litigation.”

- 3.34 The Applicant does however appreciate that there may be instances where NHS England [sic] would like to see a specific SOP or SOPs if concerns are raised. In such instances, the Applicant would be happy to provide a copy of any additional requested SOPs.

- 3.35 In addition, the Applicant has provided a concise account to explain how the pharmacy will comply with Regulations 25(2)(b) and 64. Furthermore, the Applicant has attached copies of various SOPs which demonstrate that:

3.35.1 The essential services will be secured and delivered remotely, without any interruption throughout the opening hours of the pharmacy.

3.35.2 Essential services will be provided safely and effectively to persons anywhere in England who may request the services, without face-to-face contact and not at or in the vicinity of the pharmacy premises.

- 3.36 On receipt of a query from any member of the public, patient or their carers that requests the provision of any Essential Service face to face on or in the vicinity of the premises then they will be informed that no face-to-face contact can occur between the patient or their representative and the Pharmacy staff. The member of staff will also explain that because of the NHS regulations, the pharmacy is unable to provide the provision of NHS Essential Services face to face and that they should phone/email/write in their request to the pharmacy for the team to deal with it.

- 3.37 SOPs as provided with the appeal can be found at Appendix A.

4 **Summary of Representations**

This is a summary of representations received on the appeal.

4.1 COMMUNITY PHARMACY WEST YORKSHIRE (“the LPC”)

4.1.1 Community Pharmacy West Yorkshire (“CPWY”) members still feel that their comments made in their letter to [MH] on 21 January 2022 are valid. These were as follows.

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

4.1.3 They have asked me to make the following comments:

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

- 4.1.3.2 The Applicant must give NHS England assurance that they will be able to provide pharmaceutical services throughout the contracted hours.
- 4.1.3.3 NHS England will be aware of the decision made by NHS Resolution with regard to the Pharmacy 2 U (P2U) application in Leicestershire (SHA/22233). CPWY are sure that NHS England will want to reflect on the areas where the P2U application was felt to be lacking and ensure that this application is not subject to the same or similar concerns.
- 4.1.3.4 NHS England makes reference to previous applications for Distance-Selling pharmacies that have been refused upon appeal including the West Yorkshire applications SHA/18299 - May 2016 and SHA/18727 - Sept 2017.
- 4.1.3.5 Members noted that the Applicant had provided very limited information within section 7 Pharmacy Processes of the application. Members stated that the Applicant had not provided sufficient information to provide assurance as to how the pharmacy would ensure compliance with the regulations in respect to Distance-selling contractors. This includes, but is not limited to, how deliveries will be made to patients across England, how controlled drugs will be dispensed and delivered to patients, how unwanted medication will be collected from patients for safe disposal, how the pharmacy will meet its obligations for health promotion.
- 4.1.3.6 Members noted that the pharmacy floor plans do not include any provision for a consultation room. The Applicant has stated that they intend to provide a wide-range of advanced services, many of which require a consultation room as part of the service specification.
- 4.1.3.7 The application states the pharmacy will provide the Medicines Use Review (MUR) service. This service is no longer commissioned by NHSE&I. Members questioned how up-to-date the Applicant was on pharmacy services.
- 4.1.4 CPWY members concluded that this application should be refused as the application is lacking and does not provide assurance that all essential services were likely to be secured for persons anywhere in England, nor that all essential and the specified advanced services were likely to be secured in a safe and effective manner.
- 4.1.5 If this application was to be granted, CPWY would seek that NHS England and Improvement check and gain on-going assurance that face-to-face essential services are not provided from the premises.
- 4.1.6 Members wish these comments to be taken in to consideration by the Authority [sic] and wish to be notified of the decision.

5 Summary of Observations

This is summary of observations received.

5.1 THE APPLICANT

- 5.1.1 The Applicant notes that the comments contained in the above letter are the same as the CPWY letter dated 21 January 2022 issued during [the] 45 day consultation period which the Applicant has already responded to.
- 5.1.2 However, with regards to CPWY comments about [the] consultation room and MUR, the Applicant wishes to reiterate that:

5.1.2.1 The pharmacy is a distance selling pharmacy and consultation room for essential services will NOT be needed as there will be no face-to-face consultation with the patients.

5.1.2.2 The Applicant does not intend to offer any advanced or enhanced services that would require face to face meeting/ consultation with the patients. However, the Applicant will reallocate the existing storage room to a consultation room to facilitate confidential conversation in a separate room via telephone etc. with the patients.

5.1.2.3 The Applicant is aware that the MUR is no longer commissioned and as advised previously, this was selected in error in the original application, please disregard it.

5.1.3 With regards to Regulation 25, the Applicant would like to refer to their application, subsequent information and SOP's which clearly highlight that they have been met. Therefore, the application should now be granted.

5.2 NHS ENGLAND

5.2.1 Thank you for sharing representations received in response to this appeal. It is with regret that submitting representations in relation to this appeal were missed within that initial period however NHS England would like to take this opportunity to make any final observation(s).

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

5.2.3 As per the minutes of the PSRC held 30 November 2022, the Committee [of NHS England] considered all the objections provided and that despite comments made to each of the respondent's comments, in considering whether safe and effective provision of essential services was likely to be secured and considering essential services in paragraphs 3 of Schedule 4 of the Regulations (Terms of Service) the Committee [of NHS England] was of the opinion that there was not enough evidence to be wholly satisfied this would be met.

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

6 Consideration

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

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

6.3 Since 1 April 2023, Integrated Care Boards have taken on delegated responsibility for the commissioning of pharmaceutical services. NHS England made the decision which is the subject of this appeal. NHS Resolution will issue this decision to NHS England and it is for NHS England to inform the relevant Integrated Care Board.

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

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

6.8 The Committee noted that NHS England had considered Regulation 31 and had confirmed that it did not apply "as there is no pharmacy at the same or adjacent premises to the proposed site". The Committee noted that this had not been disputed either on appeal or in subsequent representations. Based on the information before it, the Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.9 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."*

6.10 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.*

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

- 6.11.1 confirm NHS England's decision;
- 6.11.2 quash NHS England's decision and redetermine the application;
- 6.11.3 quash NHS England's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to NHS England.

Regulation 25(1)

6.12 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)

- 6.13 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.
- 6.14 The Committee noted that NHS England had confirmed, in its decision letter, that there was “no primary care provider with a patient list present within the same premises as the proposed site.” The Committee noted that this had not been disputed by any party either on appeal or in subsequent representations. 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)

- 6.15 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.
- 6.16 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.
- 6.17 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.
- 6.18 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the SOPs which the Applicant has prepared or commissioned.
- 6.19 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.
- 6.20 The Committee noted the comments at 1.5 above that “*A pharmacist shall be present throughout all core opening hours to supervise every transaction involving pharmacy or prescription only medications*”. Further the Committee noted the comments at 3.4 above with regard to a second pharmacist and in particular “*There will be a second pharmacist available during the core and any additional hours that the pharmacy operates. If the RP is required to leave the premises or takes a break (as per Working Time Directive) then the second pharmacist will assume responsibilities as the RP*”.

- 6.21 The Committee noted in SOP MYL-001 “Introduction to SOPs” under section 1 ‘Preface’ it states that the pharmacy must provide:
- 6.21.1 *“The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
- The safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else’s behalf, and the owner (applicant) of The Pharmacy or any member of staff either on or in the vicinity of the premises.”*
- 6.22 In SOP MYL-004 “NHS Essential Services” it states:
- 6.22.1 *“NHS Essential Services are provided to any patient living in England who requests such services, as stated on the website and in the pharmacy leaflet.”*
- 6.23 Further SOP MYL-026 “Responsible Pharmacist (RP)” under section 7 ‘RP Absence from the Premises’ states:
- 6.23.1 *“This is a Distance Selling pharmacy and as such, we must provide uninterrupted service throughout the opening hours of the pharmacy. The RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless another pharmacist is present.*
- There will be a second pharmacist available during the core and any additional hours that the pharmacy operates. If the RP is required to leave the premises or takes a break (as per Working Time Directive) then the second pharmacist will assume responsibilities as the RP.”*
- 6.24 The Committee noted that the Applicant at 3.5 above states *“Patients from anywhere in England may contact the pharmacy to request NHS Essential Services by phone, email, website, fax and writing during the entire proposed opening hours, without face to face contact. The website will be accessible 24 hours a day throughout the year.”* The Committee noted that the Applicant had gone on to state that *“all essential services shall be delivered in a safe and effective manner ... to persons anywhere in England who request these services, during the opening hours of the premises, without interruption...”*
- 6.25 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face-to-face contact. SOP MYL-001 “Introduction to SOPs” states:
- 6.25.1 *“Note that any reference to ‘contact’ with or ‘contacting’ a patient in relation to this SOP and other SOPs for the Pharmacy means contact other than face-to-face contact either on or in the vicinity of the premises.”*
- 6.26 The SOP goes on to state:
- 6.26.1 *“...If the RP receives a query from any member of staff as detailed above, they must:*
- Clarify to the staff member that no face-to-face contact may occur between the patient or their representative and any member of staff either on or in the vicinity of the premises.”*
- 6.27 The Committee noted that SOP MYL-004 “NHS Essential Services Standard Operating Procedure” states:

- 6.27.1 *“All communication regarding NHS Essential Services should be carried via telephone unless the patient has specifically requested to communicate by email. Video conferencing by Microsoft Teams, Zoom or other types are also permissible methods as are text messages or Facebook, fax, apps.”*
- 6.28 The Committee was aware that when the pharmacy opens, it will be the responsibility of the commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 6.29 The Committee was satisfied that the provision of essential 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.
- 6.30 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 6.31 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
- 6.32 The Committee considered whether the Applicant had explained how non- electronic prescriptions will be presented by the patient and how products will be provided.
- 6.33 From the information contained in the SOPs, provided on appeal, SOP MYL-008 'Online Orders and Exemption Checking' states:
- 6.33.1 *“Requests to collect and dispense NHS Prescriptions*
- Requests to dispense a prescription received in the post.*
- Any requests from the “contact us” section of the website.”*
- 6.34 The Committee also had regard to SOP MYL-015 'Order Delivery' which under the heading 'Choice of Delivery Method' states:
- 6.35 *“For local deliveries (up to 35 miles radius but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier should be used (see below)”. The Committee was again satisfied that the Applicant was proposing to offer the service to all of England and, given the information in the SOPs, was of the view that the Applicant would not just be using a local delivery driver.*
- 6.36 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
- 6.37 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.
- 6.38 The Committee had regard to SOP MYL-019 'Urgent Supply and Emergency Supply SOP' which describes how the Applicant will process such a request. The Committee

noted that the SOP refers 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.

- 6.39 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

- 6.40 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.

- 6.41 The Committee noted SOP MYL-008 'Online Orders and Exemption Checking' and in particular section 6 'Exempt NHS Prescriptions' which states:

6.41.1 *"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."

- 6.42 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.

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

- 6.44 The Committee noted SOP MYL-008 under the heading 'Paid NHS Prescription' it states:

6.44.1 *"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."

- 6.45 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

- 6.46 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).
- 6.47 The Committee considered the information before it contained in the SOPs as submitted by the Applicant.
- 6.48 The Committee noted SOP MYL-015 'Order Delivery' under 6.1.1 'Transfer to the Delivery Driver' states:

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

Remember to provide special delivery instructions, if any, to the delivery.

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

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

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.

At hand-over to the driver/courier:

Scan the aggregated FMD code

the system will disaggregate the unique identifiers and forward them to the NMVS for decommissioning"

- 6.49 The Committee noted within the SOPs provided, SOP MYL-015 'Order Delivery' under section 6.2 'Delivery of a prescription via Royal Mail (Not for Cold chain or CDs)' states:

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

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

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

Ensure a return address is printed clearly on the outer packaging.

Confirm details of all prescriptions to be delivered.

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

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

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

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

6.50 The Committee noted the SOP went on to state, under section 6.3 ‘Cold chain delivery via courier’:

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

Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-labile 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.

...

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. ...

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

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

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....

6.3.1 Unsuccessful cold chain delivery via courier

In the event of an unsuccessful delivery, the courier will leave a ‘Missed Delivery’ card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. The courier will keep the cold chain intact until successful delivery.

6.3.2 Cold Chain Breach

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

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

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."

6.51 The Committee noted that SOP MYL-16 'Controlled Drug (CDs) Delivery' under section 4 'Delivery of Schedule 2 & 3 Drugs' states:

6.51.1 *"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.*

An audit trail MUST be kept where delivery of CD is involved, A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet. In addition, make note of the following: -

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

CDs and any other medicines on that patient's delivery must be stored in 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.

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

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

Enter the deliveries of CD in the CD register before the medication leaves the pharmacy Premises and enter the pharmacy delivery driver/courier as the 'person collecting'.

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.

5 Successful Delivery of Schedule 2 & 3 Drugs ...

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

6 Unsuccessful Delivery of Schedule 2 & 3 Drugs by pharmacy driver

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

7 Unsuccessful Delivery of Schedule 2 & 3 Drugs – Courier

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

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

8 Note re Use of Couriers for Controlled Drug Deliveries

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

- 6.52 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.
- 6.53 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting / measuring, a registered pharmacist measures / fits them.
- 6.54 In relation to appliances, the Applicant had not completed this section of the application form and had left it blank.
- 6.55 The Committee noted the relevant SOPs with regard to Appliances which were contained within the information provided by the Applicant and in particular, SOP MYL-002 “Pharmaceutical and Legal Assessment” under section 6 ‘Measuring and Fitting Item Prescriptions’ the Applicant states:
- 6.55.1 *“Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed as follows:*
- These items are not available from this pharmacy as we do not provide a measuring and fitting service.*
- Patients should be signposted to at least two other providers of the service in their area.”*
- 6.56 SOP MYL-022 ‘Support for Self-Care, Signposting and Health Promotion’ under section 5 ‘Measuring and Fitting Prescription Items’ states:
- 6.56.1 *“If a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting, the patient should be informed that the item requested on prescription is unavailable from the pharmacy as a measuring and fitting service is not provided.*

In this case the patient should be signposted to at least two other providers of the service in their area.”

6.57 The Committee noted that the Applicant did not intend to provide any appliances and specifically those appliances which require measuring or fitting. In the event that the application is granted, the Applicant would not therefore, be able to provide any appliances to patients.

6.58 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(4) of Schedule 4.

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

6.60 The Committee noted SOP MYL-014 'Bagging-Up' under section 6 'Packaging' states:

6.60.1 *“Use packaging to suit the nature of the items being delivered and the appropriate level of protection to withstand the normal rigours of the delivery process.*

Use tamper proof seals provided in the pharmacy for all packaging and attach to the packaging so that any tampering with the packaging will be evident.

Non fragile items for local delivery can be delivered by the pharmacy delivery driver packaged using the pharmacy bags for standard prescription items.

When boxes are required, always use enforced boxes suitable for delivery purposes. DO NOT use normal cardboard boxes.

For postal items, either:

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

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

Fragile or larger medicine items should be packed using bubble packaging and filling material and re-enforced cardboard boxes to protect from damage.

Bubble wrap cold chain items and place them in styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the “FRAGILE” and “FRIDGE LINE” stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box (“cold ship” packaging) and are fully monitored (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them, and such items must not be used.”

6.61 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

6.62 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.

6.63 The Committee noted SOP MYL-011 'Repeat Dispensing' under section 5.2 'Pharmaceutical & Legal Assessment' states:

6.63.1 *"The pharmacist should telephone and speak with the patient before issuing a repeat and :*

Ensure they are taking or using, and likely to continue to take or use the medicine or appliances appropriately

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

Ensure their medication regimen has not been changed since the prescriber authorised the repeatable medication.

Ensure there have not been any changes to the patient's health since prescription was authorised

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

Any interventions or referrals (to the patient's GP or otherwise) which are deemed to be clinically significant should be recorded on the Intervention and Referral Form. The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval. "

6.64 The Committee further noted SOP MYL-011 under section 5.1 'Receipt of Prescription' states:

6.64.1 *"Complete the Pharmacy record card and attached to a RA and ensure an entry made on each occasion a dispensing takes place.*

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

6.65 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

6.66 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.

6.67 The Committee noted in the SOPs provided with the appeal, SOP MYL-011 'Repeat Dispensing' under section 5.1 'Receipt of Prescription' states:

6.67.1 *"The pharmacy staff must offer advice and explain the benefits of repeat dispensing to any patient who:*

Has a long term stable medical condition that is unlikely to change in the short to medium term; and,

Requiring regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with their prescriber.

As we are a Distance Selling Pharmacy, such advice will be provided by permissible non-face-to-face contact method with the patients.”

6.68 In addition the Committee noted under section 5.2 ‘Pharmaceutical and Legal Assessment’ SOP MYL-011 states:

6.68.1 *“Provide advice and encouragement to patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.”*

6.69 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

6.70 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.

6.71 For the return of controlled drugs, the Committee noted SOP MYL-025 ‘CD Collection from Patients and Destruction’ and in particular section 4 ‘Patient Returns Service’ which states:

6.71.1 *“This service is available to all patients living in England by the pharmacy free of charge.*

Patient and their representatives must follow the process in this SOP to return medication to the pharmacy. No direct return is permitted to the Pharmacy.

Patient/their representative must telephone the pharmacy dispensing team to make arrangements for the return of the unwanted medicines.

For CD return, patients and their representative must always speak to the RP.

The process for returning medication should be explained to the patient. Patients should be referred to the ‘Returning unwanted medication’ page on the website for information.

...

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

6.72 The Committee noted that SOP MYL-025 goes on to state, under section 5.1 ‘Return by Royal Mail’:

6.72.1 *“When items are to be returned to the pharmacy by Royal mail the pharmacist must:*

Explain the process to the patient/ their representative about the return and identify the items being returned.

Assess the items for suitability for return by Royal Mail

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

Provide details to the patients of their local process for disposal If items are not suitable for return by Royal Mail ...

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

Send the packaging to the patient / their representative along with the instructions for appropriate packing of the items to be returned.

Contact the patient/ representative to ensure that the package has been received.”

- 6.73 The Committee further noted SOP MYL-025 goes on to state, under section 5.2 ‘Handling Patient – Returned CDs from the Pharmacy Driver’:

6.73.1 *“Pharmacy drivers collecting returned medication from the patient/ representative must:*

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

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

- 6.74 The Committee noted SOP MYL-023 ‘Receipt and Disposal of Medication under section 5 ‘Return Process’ states:

6.74.1 *“Patients/representatives are not permitted to return medications directly to the pharmacy. Patients must arrange a collection with the pharmacy by telephoning the pharmacy. The unwanted medications can be collected by the following methods:*

By the pharmacy delivery driver

The pharmacy can arrange a collection from the patient via courier at the pharmacy’s cost or Royal Mail. The pharmacist may carry out risk assessment for the suitability of the items being returned prior to returns being made.

The pharmacy can arrange a collection by the pharmacy’s specialist waste management contractor

This service is available for all patients living in England. If the above methods are not suitable for the patient, then the pharmacy can signpost the patient to local pharmacies.

For further information about returning unwanted items, patients should be referred to the appropriate section of the pharmacy’s webpage.

- 6.75 The Committee noted that SOP MYL-023 under ‘Method for accepting patient returns by the Pharmacy Driver’, states:

6.75.1 *“Prior to collection, the driver must ensure to have suitable protective clothing for use whilst handling returned medication. The driver’s vehicle should be*

fully equipped with utensils as patients may have placed the medication in to the incorrect bags.

Confirm the unwanted medication booking with the patient. Medication returns should be booked via the pharmacy to ensure the medicine segregation process is followed correctly, ensuring the safe receipt of medications. Returns without a booking should only occur in exceptional circumstances, seek advice from the RP.

Check the unwanted medications for any controlled drugs. Controlled drugs should be segregated and placed into a clear bag. Refer to the SOP "CD Collection from Patients and Destruction SOP".

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

Sharps cannot be accepted by the pharmacy. Return any sharps to the customer and signpost the patient for disposal.

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

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.

The 'Patients Returns Sheet' should be completed, and relevant information should be filled out.

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

6.76 The Committee noted that the SOP went on, under section 9 'Disposal of Returned Medications, to state:

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

Unwanted medicines which have been collected by the pharmacy driver are required to be stored and placed in disposal units or containers provided ready for waste management services to collect."

6.77 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

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

6.79 The Committee noted SOP MYL-024 'Promotion of Healthy Lifestyles and Public Health Campaigns' under section 4 'Public Health Campaigns' states:

6.79.1 *"...The pharmacy will proactively 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.”

6.80 Further, in SOP MYL-024 under section 3 ‘Patient Identification’ it states:

6.80.1 *“Patients can be identified through dispensing of prescriptions. Patients can be given specific material regarding their conditions. Details of health and social care providers and local support groups can be given to patients via telephone, email, website etc.*

...

Patients who have been identified to have medical conditions (e.g. Asthma, COPD, high blood pressure, diabetes, smokers, overweight individuals) shall be delivered leaflets along with their medication as well as targeted campaigns. The pharmacy website shall also be used to promote healthy lifestyles. Newsletters shall be sent out/emailed to patients as well.”

6.81 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

6.82 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.

6.83 The Committee noted SOP MYL-024 ‘Promotion of Healthy Lifestyles and Public Health Campaigns’ under section 3 ‘Patient Identification states:

6.83.1 *“All patients will be asked to fill out a healthy lifestyle questionnaire. Questions will provide the pharmacy information for example, the patients height, weight, diet, medical conditions, lifestyle and physical activity. Patients can be sent the questionnaire which can be returned via post or complete the questionnaire on the pharmacy website. On receipt of the completed questionnaires pharmacy staff can use the results to identify and select patients who can be contacted and provided with additional information and support.*

Patients can be identified through dispensing of prescriptions. Patients can be given specific material regarding their conditions. Details of health and social care providers and local support groups can be given to patients via telephone, email, website etc.

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. Suitable advice should be given to any patients who would benefit from support for self-care and details should be recorded on the PMR system.

Patients who have been identified to have medical conditions (e.g., Asthma, COPD, high blood pressure, diabetes, smokers, overweight individuals etc.) shall be delivered leaflets along with their medication as well as targeted campaigns. The pharmacy website shall also be used to promote healthy lifestyles. Newsletters shall be sent out/emailed to patients as well.”

6.84 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

6.85 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.

6.86 The Committee noted under SOP MYL-024 'Promotion of Healthy Lifestyles and Public Health Campaigns' under section 4 'Public Health Campaigns' it states:

6.86.1 *"Each year the pharmacy is required to 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. 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.*

...

Pharmacy staff shall use prescription linked interventions for patients who have conditions such as high blood pressure, heart disease, obesity, and diabetes etc. to opportunistically provide patients with health advice [sic] over the phone or send leaflets to via the driver.

Patients can speak to the pharmacist throughout the opening hours, ensuring the uninterrupted provision of services to patients across England. Patient will be able to 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."

6.87 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

6.88 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.

6.89 The Committee noted in SOP MYL-022 'Support for Self-Care, Signposting and Health Promotion' under section 4 'Signposting' it states:

6.89.1 *"Patient Identification*

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.

Where the patient is identified to require support or advice that the pharmacy staff are unable to provide, then the patient should be signposted to a suitable provider of health and social care who is able to provide the support required. Provide the patient with contact details of at least two suitable providers if possible.

A written referral note may be provided when this is felt appropriate by the pharmacist. Where the patient is known to the pharmacy staff and the pharmacist deems it to be of clinical significance, a record of the advice given/referral may be made on the patients record.”

- 6.90 The Committee noted that in SOP MYL-024 “Promotion of Healthy Lifestyles and Public Health Campaigns” under section 7 ‘Long Term Conditions’ it states:

6.90.1 *“If it is not appropriate for the pharmacist to give advice then the patient should be signposted to an appropriate health or social care provider. Refer to the SOP on ‘Signposting’. An intervention and referral form shall be filled out with information and the referral organisation shall be noted. “*

- 6.91 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

- 6.92 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families. The Committee noted SOP MYL-022 ‘Support for Self-Care, Signposting and Health Promotion’ under section 4 ‘Support for self-care’ and 4.4 ‘Service outline’ states:

6.92.1 *“If the pharmacy staff receive a request for help, staff should provide advice to patients or their representatives on how to treat minor illnesses and how to manage long term conditions. The pharmacist can appropriately make use of patients Summary Care Records to support patients, if required.*

Any advice given should be supported with the use of available resources including leaflets and website links without any face-to-face interaction between staff and patients or their representative e.g., via telephone, Teams, email etc. The pharmacist must be informed upon the request of self-care referrals and a record of the request must be kept.

The pharmacist should provide information on the appropriate use of any suitable non prescription medications which could be used in the self-care of minor illness and long term conditions.

When appropriate, the pharmacist should make healthy lifestyle interventions opportunistically.

In line with the ‘Signposting’ service staff shall provide details and signpost to suitable health and social care providers when appropriate.

Where the patient is known to the pharmacy staff and the pharmacist deems it to be of clinical significance, details of advice given, products purchased, or referrals made shall be recorded on the patients record.”

- 6.93 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

- 6.94 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.

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

6.96 The Committee noted SOP MYL-005 "Discharge Medicines Service" states:

6.96.1 *"All referrals will be received electronically via pharmaoutcomes, this needs to be checked regularly or at least twice daily.*

All consultations must be taken over the phone in a private area of the pharmacy to maintain confidentiality

When providing this service, ALL communications with the patient/ patient's carer or other third parties shall be non-face to face and via telephone or email.

Stage 1 must be completed with 72 hours of receipt of referral (excluding hours when the pharmacy is not open for business)

When the pharmacy receives a prescription or has been made aware of a first prescription for a new medication (via DMS referral) following the patients discharge from hospital, or where the patients care has been transferred from another NHS provider, the pharmacy staff shall take the following steps:

If appropriate, the pharmacist should access the patients Summary Care Record for assistance in providing the Discharge Medicines Service

Pharmacy staff should arrange a telephone call or video call with the patient or if appropriate (bearing in mind patient confidentiality) their carer. The patient should have received a copy of the list of their medications they should be taking from the hospital. Check to see if this matches the discharge prescription. Assess the patient/ carer's understanding of the medicines that the patient should be taking.

Explain any changes that have been made to the patient's medication regimen. The pharmacist should use their clinical judgement to offer support and advice regarding their medication regimen for example, side effects, timing of doses, compliance advice etc.

Extra advice should be given for more complex regimens and high risk medications. If the patient has been prescribed inhalers, check the patient is aware on how to use their inhaler/s. If self-administered injectables have been prescribed ensure the patient has received appropriate training and is aware on how to administer the injectables.

If any of the patients' medications have been stopped, inform the patient/carer about the Disposal of Medications Service that the pharmacy provides. Refer to the 'Receipt and Disposal of Unwanted Medications' SOP for further guidance. Inform the patient of any other service that they may benefit from.

The pharmacist should use their clinical judgement and contact the patients GP to raise any possible concerns and consider any appropriate actions to deal with the concerns.

Make records of discussions and advice given to the patient. Note any concerns and any actions taken on the patients records as part of the DMS service."

- 6.97 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

- 6.98 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.
- 6.99 The Committee noted in the appeal that the Appellant states “the pharmacy website shall also be used to promote healthy lifestyles” and further states that the “website will be accessible 24 hours a day throughout the year”. The Committee also noted references throughout the SOPs to the promotion and use of the website “to ensure that patients are able to always access information about health campaigns”.
- 6.100 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

- 6.101 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).
- 6.102 Given that further information, in the form of SOPs, was provided by the Applicant with its appeal which had not been seen by either NHS England or other statutory parties, the Committee determined that the decision of NHS England must be quashed.
- 6.103 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 NHS England) or whether it was preferable for the Committee to reconsider the application.
- 6.104 The Committee noted that representations on Regulation 25 had already been made by parties to NHS England, and these had been circulated and seen by all parties as part of the processing of the application by NHS England. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.
- 6.105 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 NHS England; 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**