NHS Resolution

6 March 2026

REF: SHA/26772

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

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

APPEAL AGAINST NORTH EAST AND NORTH CUMBRIA ICB DECISION TO GRANT AN APPLICATION BY P.S. PENDERGOOD LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 379 PRINCESWAY SOUTH, TEAM VALLEY TRADING ESTATE, GATESHEAD, NE11 0TU UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

PCSE, on behalf of North East and North Cumbria ICB
Rushport Advisory, on behalf of P.S. Pendergood Ltd
Temple Bright, on behalf of Lobley Hill Pharmacy

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1 The Application

By application dated 9 June 2025, P.S. Pendergood Ltd ("the Applicant") applied to North East and North Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at Pharmacy Unit, 379 Princesway South, Team Valley Trading Estate, Gateshead, NE11 0TU 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:

1.2 "Drug Tariff part IX*

1.3 *EXCEPT items that require measuring or fitting."

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

1.5 "Not applicable as no other pharmacy in same or adjacent premises."

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

1.7 "Application 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."

Pharmacy procedures

1.8 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.

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

1.10 If you are undertaking to provide advanced services at the premises please describe how you will do so without providing any element of essential services. You must ensure that you provide sufficient information within this application form to satisfy NHS England on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England is satisfied that the full disclosure principle does not apply.

1.11 "SEE ATTACHED INFORMATION"

1.12 [the Applicant provided a copy of its SOPs]

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant to the representations on the application, had not been circulated or seen by parties.

In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and circulate these comments to parties for them to make observations on them if they so wished.

2.1 RUSHPORT ADVISORY ON BEHALF OF THE APPLICANT

2.2 "Thank you for your letter of 14 August 2025. I act for P.S. Pendergood Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

2.3 **Lobley Hill Pharmacy**

2.4 Dealing with the points raised by Temple Bright for Lobley Hill Pharmacy in order we reply as follows.

2.5 SOPs

2.6 It is normal for pharmacies to use SOPs that are sourced from third parties and it is likely that Lobley Hill Pharmacy also does this. My client has approved the SOPs for use in the proposed pharmacy.

2.7 Specific SOP points (using same numbering as the letter of objection)

2.7.1 The SOPs do not suggest that compliance with GPhC guidance is optional. Every pharmacy must operate in accordance with GPhC standards. The SOPs correctly show how the requirements of the Regulations will be met.

2.7.2 The method of communication used will be whichever is most appropriate for the service being provided and this is clear from reading the SOPs which state, that communication will *"be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages."*

2.7.3 The reference to CCGs has been removed and updated.

2.7.4 Telling a patient the location of a nearby pharmacy is not the same as "Signposting" as a pharmaceutical service and this would have been clear had Temple Bright referred to the service specification for Signposting.

2.7.5 As my client does not intend to sell medicines online this has been removed.

2.7.6 The error on the sample delivery note has been removed

2.7.7 Presenting a prescription form to a DSP is carried out using non face to face contact and the SOPs are perfectly clear on this point.

2.7.8 We do not understand the comments relating to insulin prescriptions. The SOPs are clear on how discussions with patients will take place using non face to face contact and all pharmacies use a PMR system.

2.7.9 Temple Bright appears to have confused itself about delivery methods. Different methods are used depending on which is the most appropriate and the SOPs are clear about how deliveries are carried out. Mixing up different methods of delivery to attempt confusion is not a sensible objection.

2.7.10 Royal Mail is used by many DSP to deliver prescriptions and is agreed to by patients as part of signing up with the pharmacy. It is unclear why Temple Bright believes that Royal Mail does not provide a reasonably prompt service for DSPs.

2.7.11 No cold chain courier has been appointed as the pharmacy does not yet exist.

2.7.12 No controlled drugs courier has been appointed as the pharmacy does not yet exist.

2.8 **LPC**

2.9 The LPC refers to a previous pharmacy that traded at 379 Princesway South but closed some time ago. There is no pharmacy currently at that address. My client cannot control incorrect information on a different company's website that they have failed to update.

2.10 Comments from other parties simply ask that the ICB applies the correct legal test when considering the application.

2.11 The information provided demonstrates how the legal test will be met in full and the application should therefore be approved.

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

3 The Decision

The Commissioner considered and decided to grant the application. The decision letter dated 10 October 2025 states:

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

3.1 "North East and North Cumbria ICB has considered the above application, and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.

3.2 You have a right of appeal to the Secretary of State against North East and North Cumbria 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:

3.3 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU"

Decision report

3.4 "On 24th September 2025, the Pharmaceutical Services Regulations Committee (PSRC) **approved** this **Distance Selling Premises Application** on the following basis:

3.5 **Regulation 25(2)(a)** does not apply as no primary care provider with a patient list is present within the same premises as the proposed site – **Regulation not applicable Regulation 25(2)(b)(i) -** Regulation met as the applicant demonstrated how services will be provided remotely, and without interruption throughout the given opening hours - **Regulation met**

3.6 **Regulation 25(2)(b)(ii) -** Regulation met as the applicant has demonstrated how the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services - **Regulation met**

3.7 **Regulation 31** does not apply as there is no pharmacy at the same or adjacent premises to the proposed site – **Regulation not applicable**

3.8 As the application is in respect of distance selling premises, by virtue of **Regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended**, if the applicant is subsequently included in the pharmaceutical list for the area of Gateshead Health and

Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:

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

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

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

3.8.4 The pharmacy procedures for the premises must be such as to secure

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

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

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

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

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

3.8.6.2 **Regulation 64(4)** is satisfied as the NENC ICB will not vary or remove the conditions set out in paragraph 64(3) - **Regulation met**

3.8.6.3 The HWB's **Pharmaceutical Needs Assessment** is not relevant to this application as DSP applications are excepted.

3.8.6.4 **Consultation** – One objection to the application was raised by Temple Bright on behalf of Lobley Hill Pharmacy."

4 The Appeal

In a letter dated 6 November 2025, Temple Bright on behalf of Lobley Hill Pharmacy ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for Lobley Hill Pharmacy Limited which is included in the pharmaceutical list for premises trading as Lobley Hill Pharmacy, 73 Malvern Gardens, Lobley Hill, Gateshead, NE11 9LJ.

4.2 On behalf of my client I write to appeal a decision of NHS England to grant an application by PS Pendergood Limited for inclusion in the pharmaceutical list for premises at 379 Princesway South, Team Valley Trading Estate, Gateshead, NE11 0TU in respect of distance selling premises. The decision was notified to my client by letter dated 10th October 2025.

4.3 My client's grounds of appeal are that:

4.3.1 NHS England failed to give any, or any proper, reasons for its decision to grant the application.

4.3.2 Had NHS England had proper regard to all relevant information, it should have concluded that the application did not satisfy the relevant regulatory test and refused it.

4.4 By way of background, NHS England (through PCSE) notified my client of the application by letter dated 11th July 2025. On behalf of my client, I submitted representations on the application by letter dated 19th August 2025. A copy of those representations is attached to this letter of appeal.

4.5 As NHS Resolution will note from the attached letter of 19th August 2025, the representations submitted on behalf of my client were lengthy and detailed, running to four pages in total. My client's representations submitted that the information provided by the applicant was insufficient to satisfy NHS England that the relevant regulatory test was met and provided reasons for that assertion.

4.6 My client is not aware whether the applicant responded to those representations, but no such response has been provided to my client and there is no reference to any response in NHS England's decision report.

4.7 In its decision report, NHS England stated relevantly as follows:

4.7.1 ***Regulation 25(2)(b)(i) -*** *Regulation met as the applicant demonstrated how services will be provided remotely, and without interruption throughout the given opening hours* - ***Regulation met***

4.7.2 ***Regulation 25(2)(b)(ii) -*** *Regulation met as the applicant has demonstrated how the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services* - ***Regulation met***

4.8 However, NHS England provided no reasons as to why it reached the decision that it did. That is, in light of the detailed representations made by my client, NHS England did not explain why it was satisfied that the relevant regulatory test was met.

4.9 My client asserts that, for the reasons given in the attached letter of 19th August 2025, NHS England should have refused this application. On behalf of my client, I will not repeat the contents of the 19th August 2025 letter in this letter of appeal. However, my client relies upon the contents of that letter to support its ground of appeal that the application should have been refused by NHS England.

4.10 For the reasons given above, my client therefore appeals NHS England's decision and invites NHS Resolution to conclude that the applicant has failed to provide sufficient information to satisfy the relevant regulatory test.

4.11 I look forward to hearing from you."

Letter from Temple Bright on behalf of Lobley Hill Pharmacy dated 19 August 2025

4.12 "I act for Lobley Hill Pharmacy Limited which is included in the pharmaceutical list for premises at 73 Malvern Gardens, Lobley Hill, Gateshead, NE11 9LJ.

4.13 On behalf of my client I write further to your letter of 11th July 2025 and in order to submit representations to NHS England in relation to a distance selling pharmacy application by P.S. Pendergood Limited for inclusion in the pharmaceutical list for premises at 379 Princesway South, Team Valley Trading Estate, Gateshead, NE11 0TU.

4.14 **Regulation 25**

4.15 As NHS England will be aware, the application has been submitted pursuant to regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"), being an excepted application for distance selling premises. It is therefore incumbent upon the applicant to provide suitable and sufficient information to satisfy NHS England that the applicant has in place procedures which are likely to secure the uninterrupted, safe and effective provision of all essential pharmaceutical services without face-to-face contact and irrespective of where in England the patient may live.

4.16 Whilst an applicant need not repeat every element of the Terms of Service in its application documents, where compliance with a paragraph of the Terms of Service would ordinarily require face to face contact (and would be straightforward in that context), the applicant must explain how *it* is going to achieve compliance (and therefore safe and effective provision) in the distance selling context.

4.17 It is evident from the information provided by the applicant in its application form that NHS England cannot be satisfied that the application meets the requirements of regulation 25.

4.18 Regulation 25(2)(b) requires an applicant to provide details of the pharmacy's procedures; that is, the procedures that will be adopted by the applicant in its operation of the proposed pharmacy. At section 7 of the application form, the applicant states "see attached information". It is assumed that the "attached information" is the generic SOPs produced by Rushport Advisory LLP which are described (on some of the pages) as "Approved – Dispensary Standard Operating Procedures" since no other detail or information has been provided by the applicant in support of its application.

4.19 However, the information provided within the "SOPs" is insufficient to satisfy NHS England that the requirements of regulation 25 are met by this application.

4.20 In relation to the Rushport "SOPs", as a starting point, it is not at all clear whether these SOPs "belong" to the applicant and represent how the applicant, itself, intends to provide essential pharmaceutical services. As NHS England will no doubt be aware, the "SOPs" appear to be virtually identical to SOPs submitted to NHS England in support of other applications for distance selling pharmacies. It is evident from a reading of the information provided in the Rushport SOPs that this is not information for the proposed pharmacy; rather, it is generic and "off-the-shelf" information which has been prepared not by the applicant but by Rushport Advisory and which has been used by Rushport Advisory in support of similar applications in the past.

4.21 In relation to the "SOPs" provided by Rushport Advisory, even if NHS England accepts that these set out how the applicant, itself, intends to provide pharmaceutical services, the "SOPs" are not sufficient to satisfy NHS England of the relevant regulatory requirements. By way of example:

4.22 The "SOPs" appear to suggest that the applicant's compliance with GPhC guidance for providing pharmaceutical services at a distance is not relevant to NHS England's consideration of this application (see the text in bold and capitals at page 13). This is, of course, incorrect, since paragraph 29 of the Terms of Service provides that "*An NHS pharmacist must provide pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession*."

4.23 The method by which communication with patients will take place is unclear. At pages 22 and 23 of the "SOPs", it is stated that communication will be via email/letter, phone/live audio and live video and an explanation is given as to the steps that will be taken to ensure confidentiality through those methods. However, at pages 17 and 104, the "SOPs" also refer to communication via text message. The "SOPs" give no information as to how such communication will take place safely and confidentially.

4.24 The "SOPs" refer to Clinical Commissioning Groups (or CCGs) at 119 and the NHSCB at pages 68, 96 and 104, but these bodies no longer exist.

4.25 The "SOPs" demonstrate that the proposed pharmacy would be in breach of regulation 64 in relation to the way in which it proposes to deal with patients who present at the pharmacy and seek access to pharmaceutical services. At page 17, the SOP states relevantly as follows:

4.26 ***Request for face-to-face service provision***

4.27 ***OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES.***

4.28 *If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;*

4.28.1 *Inform the person that, for NHS services, no face-to-face contact may occur on the premises between the patient or their representative and any member of staff.*

4.28.2 *Provide the person with a copy of our patient information leaflet that explains what services the pharmacy provides and why they cannot be carried out face-to-face.*

4.28.3 *Refer the person to the Responsible Pharmacist if they require any further explanation.*

4.29 Regulation 64(3) provides that it is a condition of the inclusion of a distance selling pharmacy in a pharmaceutical list that the pharmacy "*must not offer to provide pharmaceutical services…to persons who are present at (which includes in the vicinity of) the listed chemist premises*".

4.30 In the "SOPs", the applicant states that persons who present at the pharmacy and who request pharmaceutical services will be provided with a copy of the patient information leaflet (it is assumed that this is meant to read the pharmacy's practice leaflet, rather than the patient information leaflet) "that explains what services the pharmacy provides". Since the practice leaflet must give details of the pharmacy, the services it provides and how those services can be accessed, the applicant would clearly by "offering to provide" pharmaceutical services to patients who are present "in the vicinity of" the listed premises according to the "SOPs".

4.31 Information provided in relation to the online sale of over the counter medicines (page 25) is not in compliance with GPhC guidance for providing services at a distance. For example, there is no reference to identity checking.

4.32 The applicant provides a "sample of delivery note" at page 26. The wording is confusing, however, stating "Please refer to the Product Information Leaflet Rushport sops enclosed with each product". Is the applicant intending to provide a copy of the "Rushport sops" with each delivery and, if so, why?

4.33 The "SOPs" in relation to "Exempt NHS Prescriptions" imply that patients will attend at the pharmacy with their prescriptions, stating "In order to secure exemption of or remission from prescription charges **when presenting a prescription form to a pharmacy**…" (emphasis added).

4.34 The section in the "SOPs" in relation to insulin supplies (page 50) is unclear, since it fails to provide sufficient information about how the appropriate records will be checked and discussed with the patient.

4.35 Information about delivery methods is confusing. At page 72, the “SOPs” provide the following:

4.36 a. A “delivery driver” will be used for deliveries within a 30 mile radius except for cold chain items/fridge lines, where “courier” will be used at all times.

4.37 b. Royal Mail will be used for deliveries outside the 30-mile radius except for CDs where a nominated controlled drugs courier will be used.

4.38 However, this appears to contradict information elsewhere in the “SOPs”. By way of example:

4.38.1 At page 67 the “SOPs” refer only to deliveries via the local delivery driver or by courier, with no mention of Royal Mail

4.38.2 At page 73, the “SOPs” refer only to delivery drivers and courier, with no mention of the postal service.

4.39 In relation to deliveries made by Royal Mail (page 72), the applicant fails to explain how these supplies will be made “with reasonable promptness” in accordance with paragraph 5 of the terms of service.

4.40 It does not appear that the “SOPs” for prescription reception includes providing information to the patient about a time estimate for the delivery of the dispensed medication as required by paragraph 7 of the Terms of Service.

4.41 The “SOPs” refer to the use of a cold chain courier for supplies of all cold chain items, but the “SOPs” do not state which cold chain courier has been identified by the pharmacy (presumably because of the generic nature of the SOPs). NHS England cannot, therefore, be satisfied that an appropriate cold chain courier has been identified and will be used.

4.42 The “SOPs” refer to the use of a specialist controlled drugs courier, but no detail is provided about the identity of the courier to be used. NHS England cannot, therefore, be satisfied that an appropriate courier has been identified and will be used.

4.43 The “SOP” in relation to patient returns is contradictory and confusing. At page 93, the “SOP” states that patients may either arrange for a collection by the pharmacy driver or send the medication back to the pharmacy “via courier…or Royal Mail”. However, at page 95, the “SOP” states that “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”, making no mention of returns via “courier”.

4.44 **Conclusion**

4.45 Regulation 25(2)(b) requires the applicant to satisfy NHS England that the applicant will provide all NHS essential pharmaceutical services safely and effectively to patients anywhere in England who request those services.

4.46 NHS England must therefore consider Part 2 of schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. NHS England must have regard to each essential service individually and consider whether the applicant has provided sufficient information to satisfy it that the requirements of regulation 25(2)(b) would be met for each essential service.

4.47 Having regard to regulation 25(2)(b) and Part 2 of schedule 4, it is evident that the applicant has failed to provide sufficient information in relation to each individual essential service and, for example, has provided information that is unclear, contradictory or suggests that the proposed pharmacy would be in breach of its terms of service obligations. This means that NHS England cannot know how, in fact, the applicant proposes to provide all pharmaceutical services in the distance selling context.

4.48 In conclusion, in the absence of suitable or sufficient information from the applicant regarding the procedures that it will have in place for the provision of all essential services, NHS England cannot be satisfied that the requirements of regulation 25 are met. On behalf of my client I therefore invite NHS England to refuse this application."

5 Summary of Representations

This is a summary of representations received on the appeal.

Rushport Advisory on behalf of the Applicant

5.1 "Thank you for your letter of 5 December 2025. I act for P.S. Pendergood Ltd in the above application and have been instructed by my client to submit the following reply to the appeal submitted by Lobley Hill Pharmacy.

5.2 My client has instructed me to provide the attached floor plan and also a copy of the most recent version of their SOPs that have been approved for use in the pharmacy. These updated SOPs should be considered for the purposes of this appeal.

5.3 My client also asks that the Committee notes that the pharmacy will be self-contained with no access available to the public for any services.

5.4 Dealing with the points raised by Temple Bright for Lobley Hill Pharmacy in order we reply as follows.

5.4.1 SOPs

5.4.2 It is normal for pharmacies to use SOPs that are sourced from third parties and it is likely that Lobley Hill Pharmacy also does this. My client has approved the SOPs for use in the proposed pharmacy.

5.4.3 Specific SOP points (using same numbering as the letter of objection)

5.4.3.1 The SOPs do not suggest that compliance with GPhC guidance is optional. Every pharmacy must operate in accordance with GPhC standards. The SOPs correctly show how the

requirements of the Regulation 25 will be met and also quotes the standards that the GPhC sets for pharmacies (see page 13 of SOPs)

5.4.3.2 The method of communication used will be whichever is most appropriate for the service being provided and this is clear from reading the SOPs which state, that communication will *"be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages."*

5.4.3.3 The reference to CCGs has been removed and updated.

5.4.3.4 The SOPs have been updated to avoid any confusion.

5.4.3.5 As my client does not intend to sell medicines online this part of the SOPs has been removed.

5.4.3.6 The error on the sample delivery note has been removed

5.4.3.7 Presenting a prescription form to a DSP is carried out using non face to face contact and the SOPs are perfectly clear on this point. The SOP has also been updated to avoid any confusion.

5.4.3.8 My client does not understand the comments relating to insulin prescriptions. The SOPs are clear on how discussions with patients will take place using non face to face contact and all pharmacies use a PMR system.

5.4.3.9 Temple Bright appears to have confused itself about delivery methods. Different methods are used depending on which is the most appropriate and the SOPs are clear about how deliveries are carried out. Mixing up different methods of delivery to attempt confusion is not a sensible objection.

5.4.3.10 Royal Mail is used by many DSP to deliver prescriptions and is agreed to by patients as part of signing up with the pharmacy. It is unclear why Temple Bright believes that Royal Mail does not provide a reasonably prompt service for DSPs.

5.4.3.11 No cold chain courier has been appointed as the pharmacy does not yet exist. There are a number of different cold chain couriers that provide services to pharmacies and the SOPs set out the method of delivery and standards that will be used.

5.4.3.12 No controlled drugs courier has been appointed as the pharmacy does not yet exist. There are a number of different controlled drug couriers that provide services to pharmacies and the SOPs set out the method of delivery and standards that will apply.

5.4.4 We ask that this appeal is refused as the application from P.S. Pendergood Ltd provides evidence that shows that the legal test will be met in full and we look forward to hearing from you in due course."

Boots UK Ltd

5.5 "Thank you for your letter dated 5th December 2025 informing us of the above appeal.

5.6 Boots UK Ltd have no further comments to make but respectfully ask that NHS Resolution inform us of the decision in due course."

6 Summary of Observations

This is summary of observations received.

Temple Bright, on behalf of the Appellant

6.1 "I write further to your letter of 9th January 2026. On behalf of my client, Lobley Hill Pharmacy Limited, I comment on the representations received on my client's appeal as follows.

6.2 **Boots Pharmacy**

6.3 My client has no comments to make on the contents of this letter.

6.4 **Rushport Advisory LLP on behalf of the applicant**

6.5 My client notes that a further version of the Rushport SOPs has now been provided by the applicant, asserting that these SOPs represent how the applicant, itself, proposes to provide pharmaceutical services (rather than the SOPs previously provided).

6.6 Even if NHS Resolution disregards the confusing picture painted by the applicant supplying multiple versions of how it proposes to provide pharmaceutical services (and the inherent uncertainty that this creates), my client maintains that the new SOPs are still insufficient to satisfy NHS Resolution that the relevant regulatory test will be met by this application. In particular (and without repeating comments made in respect of the previous "SOPs" which my client maintains continue to apply to the new "SOPs"):

6.6.1 In relation to the method of communication, the response by Rushport misses the point being made. The "SOPs" detail methods of communication that may be used by the proposed pharmacy to contact the patient (pages 21 to 24). This includes contacting patients by text message. In respect of some forms of communication, the "SOPs" detail how patient confidentiality will be maintained. However, no such information is given in relation to maintaining patient confidentiality where text messaging is used.

6.6.2 In relation to the Pharmacy First "SOP" (pages 39 to 48) there is reference (at pages 45 and 48) to confirming the "delivery time" with the patient and ensuring that "this delivery time is suitable" or "still meets

the need for the emergency supply". However, the applicant fails to identify what delivery method will be used for the provision of this service and what will happen if the delivery time is not suitable.

6.6.3 The "SOP" for EPS nomination states (at page 62): "Once the patient has made their choice ask them to complete and sign a nomination consent form. This form should be stored securely on the PMR to provide evidence of the patient's selection." However, the applicant fails to explain how this will be carried out in the distance selling context, including:

6.6.3.1 how the nomination form will be made available to the patient

6.6.3.2 how it will be returned to the pharmacy free of charge

6.6.3.3 how this will be undertaken whilst also ensuring

6.6.3.3.1 that medication is received "with reasonable promptness" as required by the terms of service

6.6.3.3.2 the requirement in the SOP that all nominations and changes must be completed within "one working day" (page 63)

6.6.4 The "top tips for EPS" "SOP" states (at page 66): "Make sure you get all non-age exempt patient to sign a token – this includes each issue of a repeat dispensing regime." However, the "SOP" fails to explain how this will be done in the distance selling context (ie how the patient will "sign" the token and return it to the pharmacy free of charge, particularly having regard to the need to supply medication with reasonable promptness in accordance with the terms of service).

6.6.5 In relation to deliveries made by Royal Mail, the applicant fails to explain how these supplies will be made "with reasonable promptness" in accordance with paragraph 5 of the terms of service.

6.6.6 It does not appear that the "SOPs" for prescription reception (pages 25 to 29) includes providing information to the patient about a time estimate for the delivery of the dispensed medication as required by paragraph 7 of the Terms of Service.

6.6.7 The "SOP" for repeat dispensing (page 143) refers to prescriptions being collected from the patient's GP surgery by the pharmacy. However, this method of prescription reception is not mentioned in the "SOP" for prescription reception, and it is unclear how this would be provided in the distance selling context having regard to the fact that a national service must be provided.

6.6.8 The "SOP" for the Discharge Medicines Service (page 123) refers to patients who have collected their medication from the pharmacy (eg, "it is possible that the prescription may have been collected by the patient or a representative and either: the patient was unable to discuss their medicines at the point of collection"). In-person collection of medication

from a DSP is not permitted and is a clear indication of a breach of the relevant regulatory test.

6.6.9 The customer complaints "SOP" (page 129) refers to medication which has been supplied to the patient from the "warehouse". No other reference to a "warehouse" is made in the "SOPs" (except in relation to courier-delivered medication) so it is not clear what this is a reference to, but since all medication must be supplied from the listed premises, supply from a "warehouse" (ie not the pharmacy) would be a clear breach of the terms of service.

6.6.10 Additionally, the customer complaints "SOP" refers to the "non-arrival of dispatched medication" but only refers to medication dispatched via Royal Mail – no reference is made to medication delivered via the pharmacy's delivery driver or the courier.

6.7 For the reasons given above and those given in my client's letter of appeal, on behalf of my client I invite NHS Resolution to uphold my client's appeal and refuse this application.

6.8 I look forward to hearing from you."

7 **Additional comments**

Rushport Advisory LLP on behalf of the Applicant submitted further observations after the consultation period had ended with their further observations being submitted on 23 January 2026, when in fact the consultation period had terminated on 19 January 2026.

7.1 "I act for P.S. Pendergood Ltd in the above application and have been instructed by my client to submit this response to the comments from Lobley Hill Pharmacy Ltd in relation to my client's appeal.

7.2 Dealing with the specific points raised in the appeal we reply as follows.

7.3 SOPs

7.4 SOPs are supposed to be "living" documents, in that they should be regularly updated to reflect best practice and my client has demonstrated that they will do exactly that. There is nothing "confusing" about updating a document.

7.5 Premises

7.6 My client's SOPs provide detail for how any request for face to face services will be dealt with (page 17). My client's floor plan shows that the premises are not retail premises. My client will not provide services to patients face to face at the premises and patients will not be able to access the premises.

7.7 GPhC

7.8 Page 13 of my client's SOPs set out the key principles that the GPhC has published and the GPhC is referenced at various points throughout the SOPs.

The text highlighted by Temple Bright is entirely correct and in no way implies that GPhC guidance is not relevant.

7.8.1 **Contacting Patients**

7.8.2 Pages 21 to 24 start by setting out policies that ensure confidentiality of patient communication and deals specifically with the requirement for confidentiality. Text messaging is used across the NHS to contact patients and is via a company account (ie desktop pc) rather than a normal phone.

7.8.3 **Pharmacy First**

7.8.4 Any delivery of medicines required following a Pharmacy First consultation will take place in accordance with the specific delivery SOPs covering controlled drugs, fridge line, normal items, urgent items. Methods of delivery for each type of medication are clearly explained in the relevant SOPs. A delivery time that suits the patients will be agreed and that is why a delivery time is checked to make sure that it is suitable.

7.8.5 **Nomination Form**

7.8.6 Page 62 clearly states that nomination forms are available on the pharmacy's website. Patients who choose to use a distance selling pharmacy will be choosing to access a pharmacy that operates online. Patients can also change their nomination using the NHS app (page 63, 12.10). Forms can be emailed to the pharmacy.

7.8.7 It is unclear why Temple Bright has mixed up patient nominations with the delivery of a prescription item with reasonable promptness and this may simply be their misunderstanding of the processes involved.

7.8.8 **EPS**

7.8.9 The commentary on EPS is listed as "top tips" and is not a regulatory requirement.

7.8.10 In the event that a patient does not sign the token, pharmacy staff can sign it on their behalf to claim the exemption from prescription charges. The pharmacy records all exemptions as per SOP 6.9. For deliveries by the pharmacy's own driver the driver will request the patient to complete the token (SOP 19.11 point 3).

7.8.11 **Royal Mail**

7.8.12 Royal Mail is used by many DSPs to deliver prescriptions and patients are informed of their delivery method and will have agreed to it. A patient who chooses to use a DSP is aware that their medication will be delivered to them and also informed of the estimated delivery time. It is unclear why Temple Bright believes that delivery via Royal Mail is anything other than reasonably prompt for patients who have accepted it as their delivery method. What is "reasonably prompt" will differ depending on the type of pharmacy a patient uses. For a high street

pharmacy a patient might expect their prescription within a few minutes of entering a pharmacy. For a DSP the timescales will naturally be longer.

7.8.13 Temple Bright then makes reference to supplies that are urgent. If a patient required an item urgently, for example an antibiotic required immediately, then they would not use a pharmacy that was required to deliver the item to them in the post. For Urgent/ Emergency Supply at the request of a doctor / patient there is a specific SOP (SOP 16) that explains how deliveries would be prioritised.

7.8.14 **Estimate of Delivery Time**

7.8.15 The requirement to provide a patient with an estimate of delivery time is found at the Order Delivery SOP 19.8. Additional information such as tracking numbers is also provided as appropriate (see SOP 19.14 point 8, SOP 19.16 point 15, SOP 8 point 39, SOP 14.5, SOP 16.11)

7.8.16 **Repeat Dispensing**

7.8.17 It is unclear what point Temple Bright is making in relation to how prescriptions are received by the pharmacy. Over 99% of prescriptions are now EPS, but there are still some paper prescriptions used and these can be sent in the post or collected from a GP surgery. There is no requirement to collect paper prescriptions in person from all GP surgeries in England and the postal service would be used for surgeries that are too far away for the pharmacy driver to collect from.

7.8.18 **Discharge Medicines Service**

7.8.19 SOP 28.18 (referred to by Temple Bright) is entitled “Examples where normal flow of patients through the service may not be appropriate” and sets out some examples of why it may not be appropriate to provide the DMS service or where the service would be stopped. A patient may use an alternate pharmacy such as a high street pharmacy to collect some medicines, particularly post discharge from hospital. Patients may use one pharmacy for Stage 1 or the DMS process and another for Stage 2 (as set out in point 4 of SOP 28.18) and the pharmacist should be aware of this possibility. All medicines supplied by my client’s pharmacy will be supplied in accordance with the delivery SOPs and medicines cannot be collected by patients at the premises.

7.8.20 Throughout the SOPs there is reference to guidance produced by the NHS, GPhC or Community Pharmacy England on a range of services. This guidance is rarely, if ever, written specifically for distance selling pharmacies and some of the guidance or examples referred to would definitely not apply at a DSP. This guidance is still helpful, and it is important for a pharmacist to be aware of how the whole system works and that patients may “collect” medicines from a different pharmacy but still use my client’s distance selling pharmacy for follow-up services (as permitted under the relevant service specification and noted in SOP 28.18).

7.8.21 My client's pharmacy will follow its own procedures for all medicine supplies and contact with patients.

7.8.22 My client will not permit any collection of medicines or access to any NHS service from the pharmacy premises.

7.8.23 **Customer Complaints**

7.8.24 The SOP referred to relates to non-arrival of medicines were to be delivered via Royal Mail and refers to the warehouse used by Royal Mail to sort parcels for delivery. We accept that the wording could be improved and this will be amended. The remainder of the points make it clear that this process refers to Royal Mail and their facilities.

7.8.25 The failed delivery process for items delivered via courier or the pharmacy delivery driver is completely different from the process used by Royal Mail. Failed delivery for controlled drugs is found at SOPs 23.8 and 23.9, for standard deliveries via the delivery driver see 19.13 and cold chain at 19.17.

7.8.26 The list of matters that a patient may wish to make a complaint about is not intended to be exhaustive nor does it form part of the legal test.

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

8 Consideration

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

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

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

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

Regulation 31

8.5 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") at or from -

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

(ii) adjacent premises; and

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

8.6 The Committee noted that in response to the question in the application form on this point, the Applicant stated "*Not applicable as no other pharmacy in same or adjacent premises*". In its decision report, the Commissioner stated that "*Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site.*" This had not been disputed on appeal.

8.7 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

(2) NHS England must refuse an application to which paragraph (1) applies—

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

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

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

(ii) the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the

services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy 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.*

Regulation 25(1)

8.10 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)

8.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application in which the Applicant states "*Application 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*". The Commissioner, in its decision report, stated that "*Regulation 25(2)(a) does not apply as no primary care provider with a patient list is present within the same premises as the proposed site*". The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

8.12 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 and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

8.13 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, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.

8.14 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.

8.15 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, that evidence put forward has taken the form of the updated SOPs provided on appeal, which the Applicant has prepared or commissioned.

8.16 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 in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

Essential services will be provided on an uninterrupted basis

8.17 The Committee considered how the Applicant would provide essential services without interruption and noted the information in the Applicant's SOPs under the following headings:

8.18 SOP 1: 'Introduction and Background to SOPs':

8.18.1 "*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide;

The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services.

The safe and effective provision of pharmaceutical 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 of

this pharmacy or any member of staff either on or in the vicinity of the premises."

8.19 SOP 33 'The Responsible Pharmacist':

8.19.1 "*33.9 Absence of the RP"*

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted.

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

8.20 Based on the information provided to it, the Committee was satisfied that the provision of services would be without interruption.

Provision of services across England

8.21 With regard to essential services being available to persons anywhere in England, the Committee noted the following information in the Applicant's SOPs:

8.22 SOP 1: 'Introduction and Background to SOPs'

8.22.1 "*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide;

The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services."

8.23 SOP 3: "Procedures for NHS Pharmaceutical Services"

8.23.1 "*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet*."

8.24 Based on the information provided to it, the Committee was satisfied that the provision of essential services would be across England.

Without face to face contact

8.25 The Committee noted the Appellant's concern regarding potentially ambiguous wording in the SOPs about the provision of services without face to face contact. In particular, the Appellant highlighted the reference to "presenting a prescription form to a pharmacy". The Committee considered this point in light of the updated SOPs.

8.26 The Committee noted SOP 1, 'Introduction and Background to SOPs', under the heading, '1.3 Overriding Provisions Applicable to All SOPs', states:

8.26.1 "*All pharmacy staff must note that this pharmacy operates in accordance with specific approval under the Regulations and these premises are 'Distance Selling Premises'. In order to comply with our terms of service, this pharmacy will provide;*

The safe and effective provision of pharmaceutical 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 of this pharmacy or any member of staff either on or in the vicinity of the premises.

…

All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises.

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises."

8.27 SOP 3: 'Procedures for NHS Pharmaceutical Services' states:

8.27.1 "*3.1* ***Communication Channels***

All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages.

The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises.

Text messages must be sent via the pharmacy computer system so that they can be logged for future reference.

8.27.2 ***3.2 Request for face-to-face service provision***

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation."

8.28 Further, the Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face to face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

8.29 In its application the Applicant stated that it intended to provide "*NMS (remotely with consent where required)*". The Committee noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call.*"

8.30 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.

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

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

Dispensing of drugs and appliances

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

8.34 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

8.34.1 "*…Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so [sic].*"

8.35 SOP 6 'Prescription Receipt & Exemption Checking' states:

8.35.1 "*6.2 Scope*

All online services including the following:

Requests for dispensing Private Prescriptions.

NHS Prescriptions."

8.35.2 "*6.7 Administration Checks*

Check all prescriptions received in the post against printed and written prescription reception forms. *Check the corresponding prescription has been received in the post and match with the received and printed order by confirming the unique voucher number, patient name, address and DOB*."

8.36 SOP 19 'Order Delivery' states:

8.36.1 "*19.6 Choice of Delivery Method'*

For items ***other than*** *cold chain / "fridge line" items, local deliveries (up to 30 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 must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used (see below). [Applicant's emphasis]*

For Emergency Supplies our delivery driver will deliver the medication if possible and if the distance for delivery is considered to be too far for the driver then a courier should be booked to make the delivery."

8.37 The Committee noted the Appellant's comment that the SOP for Repeat Dispensing refers to prescriptions being collected from the patient's GP surgery by the pharmacy, but that this method is not mentioned in the SOP for prescription reception. The Committee noted the Applicant's response that "*Over 99% of prescriptions are now EPS, but there are still some paper prescriptions used and these can be sent in the post or collected from a GP surgery. There is no requirement to collect paper prescriptions in person from all GP surgeries in England and the postal service would be used for surgeries that are too far away for the pharmacy driver to collect from.*"

8.38 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

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

Urgent supply without a prescription

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

8.41 The Committee noted the information in the Applicant's SOPs under the heading 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means 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.

8.42 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

8.43 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.

8.44 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking' states:

8.44.1 "*6.9 Exempt NHS Prescriptions*

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

8.45 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.

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

8.47 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking' states:

8.47.1 *"6.12 Paid NHS Prescription*

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.

The reverse of the prescription should be fully completed.

If an item is available and cheaper to buy consult the pharmacist."

8.48 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

8.49 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).

8.50 The Committee noted SOP 19 'Order Delivery' states:

8.50.1 *"19.10 Transfer to the Delivery Driver*

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

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

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

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

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

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

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

At hand-over to the driver / courier ensure that any current falsified medicines regulation or guidance is followed."

8.50.2 "***19.11 Delivery of prescription to patient or representative address***

The delivery driver must not enter the patient or representative's home unless invited to do so at the time.

The patient should be referred to the pharmacist if they have any query about how to use their medication safely and appropriately.

Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. *Patient confidentiality should be maintained at all times, especially if delivering to a representative.*

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet*. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.*

If necessary, collect any medication returns*. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance*."

8.50.3 "***19.12 Successful delivery***

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

8.50.4 "*19.13* ***Unsuccessful Delivery***

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

8.50.5 **"*19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)***

Follow preparation for delivery process. The pharmacist must 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.

The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

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."

8.50.6 **"*19.16 Cold chain delivery via courier***

Explanatory Notes:

See "Bagging Up" SOP for cold chain packaging guidance

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

Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and

effectiveness are always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.

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 must 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.

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

A delivery must 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 must 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.

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number."

8.50.7 "*19.17 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 along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

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

8.50.8 *"19.18 Breach of Integrity of Cold Chain*

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.

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

8.51 SOP 23 'Controlled Drugs: Delivery' states:

8.51.1 "***23.5 Delivery of Schedule 2 & 3 CDs***

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

CDs must be 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 the lockable compartment of the delivery van and out of sight.

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

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

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

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

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

8.51.2 *"**23.7 Successful Schedule 2 & 3 Delivery***

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

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."

8.51.3 *"**23.8 Unsuccessful Schedule 2 & 3 Delivery via 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 where appropriate with an explanation. These must then be

secured in the CD cabinet where appropriate."

8.51.4 "***23.9 Unsuccessful Schedule 2 & 3 Delivery via courier***

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

8.51.5 **"*23.10 Note re Use of Couriers for Controlled Drugs 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."

8.52 The Committee noted the Appellant's concern that the Applicant had not explained how items would be delivered with reasonable promptness by Royal Mail. The Committee noted the Applicant's response that "*Royal Mail is used by many DSPs to deliver prescriptions and patients are informed of their delivery method and will have agreed to it. A patient who chooses to use a DSP*

is aware that their medication will be delivered to them and also informed of the estimated delivery time." For urgent deliveries, the Committee noted that point 16.11 of the SOPs describes how the Applicant would deal with the delivery of urgent and emergency supply items. The Committee concurred with the Applicant that patients choosing to use a distance selling pharmacy will be aware that their items will need to be delivered and that there will therefore be a longer wait than if they had chosen to use a non-distance selling pharmacy.

8.53 The Committee further noted the Appellant's comment that the SOP for the Discharge Medicines Service refers to patients who have collected their medicines from the pharmacy i.e. "*it is possible that the prescription may have been collected by the patient or a representative and either: the patient was unable to discuss their medicines at the point of collection*". The Committee noted the Applicant's response that SOP 28.18 which is referred to "*…is entitled "Examples where normal flow of patients through the service may <u>not</u> be appropriate" and sets out some examples of why it may not be appropriate to provide the DMS service or where the service would be stopped. A patient may use an alternate pharmacy such as a high street pharmacy to collect some medicines, particularly post discharge from hospital. Patients may use one pharmacy for Stage 1 or the DMS process and another for Stage 2 (as set out in point 4 of SOP 28.18) and the pharmacist should be aware of this possibility. All medicines supplied by my client's pharmacy will be supplied in accordance with the delivery SOPs and medicines cannot be collected by patients at the premises*." The Committee also noted the numerous references throughout the SOPs to patients being unable to access services at the pharmacy premises.

8.54 The Committee noted the Appellant's comment that the SOP for Customer Complaints refers, at page 129, to a "warehouse", which would be a breach of terms of service. The Committee noted the Applicant's response that this refers to the non-arrival of medicines being delivered by Royal Mail, and refers to Royal Mail warehouse. The Committee noted that the Applicant intends to adjust the wording to clarify the meaning.

8.55 The Committee also noted the Appellant's comment that the SOP for Customer Complaints refers to the non-arrival of medication, but only refers to medications delivered via Royal Mail. The Committee was of the view that sufficient information had been provided as detailed above, regarding the non-delivery of medication by other means.

8.56 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.

8.57 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.

8.58 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated *"Drug Tariff part IX* *EXCEPT items that require measuring or fitting".* The Committee noted the Applicant's SOPs state:

8.59 SOP 9 ‘Pharmaceutical & Legal Assessment’:

8.59.1 “***9.9 Items Requiring Measuring and Fitting***

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

8.60 SOP 26 ‘Support for Self-Care, Signposting and Health Promotion’ states:

8.60.1 *“**26.14 Items Requiring Measuring and Fitting***

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

8.61 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(4) of Schedule 4.

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

8.63 The Committee noted that SOP 18 ‘Bagging-Up’ states:

8.63.1 **“*18.7 Choice of Packaging***

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 for local delivery 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.

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

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***

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

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (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."

8.64 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

8.65 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.

8.66 The Committee noted SOP 34 'Repeat Dispensing' states:

8.66.1 "***34.10 Prescription Reception***

The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.

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

8.66.2 **"*34.11 Pharmaceutical & Legal Assessment***

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only

requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

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

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

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

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

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

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

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

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."

8.67 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

8.68 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.

8.69 The Committee noted SOP 34 'Repeat Dispensing' states:

8.69.1 "***34.10 Prescription Reception***

Appropriate advice about the benefits of repeat dispensing must be given to any patient who:

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

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.

Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them."

8.69.2 "*34.11 Pharmaceutical & Legal Assessment*

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

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

8.70 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

8.71 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.

8.72 The Committee noted SOP 24 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

8.72.1 "***24.5 Patient Returned Medication***

This service is available to all patients living in England.

Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

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

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

The process for returning medication must be explained to the patient.

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 – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician.

8.72.2 **"*24.7 Return by Royal Mail***

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

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

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

8.72.3 **"*24.8 Handling Patient-Returned CDs from Delivery Driver***

Drivers need to:

Be aware that they cannot accept patient returns from patients without prior arrangement.

The driver must 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.

Pharmacy staff need to:

If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.

As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date."

8.73 SOP 25 'The Safe and Effective Receipt and Disposal of Medicines' states:

8.73.1 "***25.6 Process for Patients to Return Medication***

Patient Returned Medication

Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in England.

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

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

Check the relevant PMR to identify any hazardous / dangers drugs or items that have been dispensed and could potentially form part of the return.

Ask the patient to identify the type of medication being returned.

If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.

Go through the "unwanted medicines card" (available from the CPE website) over the phone with the patient."

8.73.2 *"**25.7 Process for accepting patient returns by the Driver***

Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.

Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags

Wear appropriate protective clothing where there is a requirement to handle any returned waste.

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

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

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

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

Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.

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

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

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

Ensure medicines are not visible in the vehicle at all times."

8.73.3 ***"25.9 Return by Royal Mail***

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

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

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

8.73.4 *"**25.10 Disposal of returned medicines***

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

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

8.74 Based on all of the information before it, 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

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

8.76 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

8.76.1 *"**27.3 Identification of patients for promotion of Healthy Lifestyles***

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

***Active patients** will be 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. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask 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.*

***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 / diabetes etc.*

***As part of repeat dispensing process (or during any other interaction with a patient)** staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.*

Leaflets will be delivered to patients with their medication. Those identified 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. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone.

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's

Summary Care Record / National Care Records Service to see if it assists in identifying what areas to provide advice on."

8.76.2 "***27.4 Health Campaigns & Community Engagement Exercise***

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

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

…

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

8.77 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

8.78 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.

8.79 The Committee noted SOP 27, 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

8.79.1 "*27.6 Long Term Conditions*

If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. *Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.*

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients

who smoke or who are overweight) *the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets.*"

8.79.2 "***27.7 Identification of patients for Support with Long Term Conditions***

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients *will be 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. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask 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.*

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 / diabetes etc.*

As part of repeat dispensing process (or during any other interaction with a patient) *staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.*

Leaflets will be delivered to patients with their medication. Those identified 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. The website, app and email newsletters will also be used to promote healthy lifestyles."

8.80 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

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

8.82 The Committee noted SOP 27, 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

8.82.1 "***27.4 Health Campaigns & Community Engagement Exercise***

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

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

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

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

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

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

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

8.83 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

8.84 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.

8.85 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

8.85.1 "***26.10 Other Provider Organisations and Support Details***

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

8.85.2 *"**26.12 Signposting***

Service Description

To minimise inappropriate use of health and social care services and support services, patients 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 must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

8.85.3 *"**26.13 Patient Identification***

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

> *requires advice, treatment or support that we cannot provide; but we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.*

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

8.86 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

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

8.88 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

8.88.1 *"**26.8 As part of repeat dispensing process / medicine sale or during any other interaction with a patient** staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for selfcare they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:*

treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

on changes to the patient's lifestyle."

8.88.2 "***26.9 Service outline***

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

If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in delivery of the service.

The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."

8.89 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

8.90 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

regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

8.92 The Committee considered the Appellant's concern regarding the wording of the SOPs, specifically the reference to prescriptions being "collected by the patient", and was satisfied, in light of the wider provisions of SOP 28, that the Discharge Medicines Service would be delivered through non-face-to-face methods.

8.93 The Committee noted SOP 28 'Discharge Medicines Service ('DMS')' states:

8.93.1 ***"28.3Process***

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

8.93.2 *"**28.4 Consent***

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP.

8.93.3 *"**28.5 DMS Stages***

It is expected that all patients referred to the pharmacy will receive all three stages of the service.

Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."

8.93.4 ***"28.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)***

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted

on the discharge referral) and to seek clarification about the discharge referral."

8.93.5 **"*28.7 Considering the appropriateness of any medication changes prior to discharge***

DMS requests will not necessarily all be in the same form.

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

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral,

and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHS GUIDANCE."

8.93.6 **"*28.8 DMS Stage 2***

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the

general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication

Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy as received a request for Stage 2 of the DMS service either from Stage 1 or

> *Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 that this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND*
>
> *The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide*

Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

> *Review / perform a further review of any prescription*
>
> *Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service.*
>
> *Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.*
>
> *Where you see areas of concern, raise those issues as appropriate with the patient's GP*
>
> *Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."*

8.93.7 ***"28.9 DMS Stage 3***

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to

establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines.

8.94 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

8.95 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.

8.96 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

8.96.1 ***"26.11 Health promotion zone on our website***

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

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 includes 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."

8.97 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.

Other matters

8.98 With regard to the Appellant's comment that the SOPs do not reflect how patient confidentiality will be maintained for text messages, the Committee noted the Applicant's confirmation that "*Text messaging is used across the NHS to contact patients and is via a company account (ie desktop pc) rather than a normal phone.*" In addition, the Committee considered that a text can be sent without containing patient sensitive information. The Committee noted that deliveries arising from Pharmacy First consultations are covered under the general SOP for deliveries, this being SOP 19. Whilst timescales for deliveries via Royal Mail within the context of reasonable promptness are not referenced anywhere, the Committee accepted the Applicant's comments that this would be dependent on the specific circumstances of the patient interaction and medicines required. The handling of EPS nominations and patient interactions arising are reflected in the Applicant's response that "*Page 62 clearly states that nomination forms are available on the pharmacy's website. Patients who choose to use a distance selling pharmacy will be choosing to access a pharmacy that operates online. Patients can also change their nomination using the NHS app (page 63, 12.10). Forms can be emailed to the pharmacy.*" (SOP 12). The Committee was satisfied that the completion of nomination forms would be achieved on a non-face to face basis.

Summary

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

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

8.100.1 confirm the Commissioner's decision;

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

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

8.101 The Committee had sight of additional evidence in the form of the Applicant's updated SOPs provided with its representations, which were not available to the Commissioner. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

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

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

by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

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

9 Decision

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

9.2 The Committee:

9.2.1 quashes the decision of the Commissioner; and

9.2.2 redetermines the application as follows -

9.2.2.1 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;

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

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

9.2.2.4 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

9.2.2.5 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

9.2.3 The application is granted.

Case Manager
Primary Care Appeals