

28 November 2024

REF: SHA/26298

**APPEAL AGAINST LEICESTER, LEICESTERSHIRE AND
RUTLAND ICB DECISION REGARDING A BREACH
NOTICE AT PINFOLD PHARMACY, 26 PINFOLD GATE,
LOUGHBOROUGH, LEICESTERSHIRE, LE11 1BE**

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

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

1 Outcome

- 1.1 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations I substitute the decision of the Commissioner to issue the Breach Notice with a decision to issue a breach notice stating that the failure to open for the directed hours on 26 December 2023 is a breach of paragraph 23(1)(e).

A copy of this decision is being sent to:

LP SD Fifty Eight Ltd
East Midlands Primary Care Contracting Team, on behalf of Leicester, Leicestershire and Rutland ICB

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1 The Breach Notice

A Breach Notice dated 30 August 2024 was sent to LP SD Fifty Eight Ltd (“the Appellant”) in respect of Pinfold Pharmacy, 26 Pinfold Gate, Loughborough, Leicestershire, LE11 1BE.

- 1.1 **“Name of contractor:** LP SD Fifty Eight Limited
- 1.2 **Pharmacy Name:** Pinfold Pharmacy
- 1.3 **Address of premises:** 26 Pinfold Gate, Loughborough, Leicestershire LE11 1BE
- 1.4 **Date of inclusion in the pharmaceutical list for the area of Leicestershire Health and Wellbeing Board:** 26 October 2023
- 1.5 This is a Breach notice issued under regulation 71 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- 1.6 **Breaches of terms of service: breach notices**

71.(1) Where an NHS chemist (C) breaches a term of service and the breach is not capable of remedy, the NHSCB may by a notice (“a breach notice”) require C not to repeat the breach.

(2) To be valid, the breach notice must include—

(a) the nature of the breach; and

(b) an explanation of how C’s rights of appeal under regulation 77(1)(c) may be exercised.

(3) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that C is required to provide, the breach notice may provide that, as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, the NHSCB is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(6) in respect of that period.

(4) The breach notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 91(6) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.

1.7 Nature of the breach

- 1.8 Following an assessment of the need for the provision of pharmaceutical services on Tuesday 26 December 2023, and taking into account which pharmacies would be open on that day, Leicester, Leicestershire and Rutland Integrated Care Board (ICB) directed

LP SD Fifty Eight Limited (the contractor) to open the above-mentioned pharmacy between 14:00 and 16:00hrs on Tuesday 26 December 2023. No appeal was made against the decision to issue the direction.

- 1.9 Upon noting that no claim had been made by the contractor, the ICB contacted the contractor to establish why this was the case. A copy of the responsible pharmacist log or other assurance was requested for that day which would evidence when the pharmacy opened. This was not received by the ICB. A remedial notice was also issued so that the pharmacy could send in assurance of opening on the directed day, but this was not provided.
- 1.10 This failure to ensure the pharmacy premises were open for the provision of pharmaceutical services between 14:00 and 16:00hrs on Tuesday 26 December 2023 was referred to the Pharmaceutical Services Regulations Committee (PSRC) on 20 August 2024. Having taken into account the reasons why the pharmacy did not open on the specified day, the PSRC was of the opinion that there was no good cause. It was therefore satisfied that the contractor breached paragraph 23(1)(c), Schedule 4 on Tuesday 26 December 2023 and determined that it is appropriate to issue this breach notice.
- 1.11 You are required to not repeat the breach again.
- 1.12 You have a right of appeal to the Secretary of State against the issuing of this breach notice. Should you choose to appeal then you should send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this notice to nhsr.appeals@nhs.net or:
- 1.13 Primary Care Appeals
NHS Resolution
8th Floor 10 South Colonnade,
Canary Wharf,
London,
E14 4PU
- 1.14 Please note that should you fail to comply with the requirements of this breach notice we reserve the right to exercise our powers to take further action in relation to your inclusion in the pharmaceutical list in respect of the above named premises. This may include removal of the premises from the relevant pharmaceutical list under regulation 73 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013."

2 The Appeal

In an email dated 4 September 2024 and addressed to NHS Resolution, the Appellant appealed against the Commissioner's decision. The grounds of appeal are:

- 2.1 "I am writing in response to the breach notice issued to Pinfold Pharmacy regarding the failure to adhere to the stipulated opening hours. We were previously unaware of this directive and regret any inconvenience caused.
- 2.2 Pinfold Pharmacy underwent a change in ownership on October 26, 2023. Unfortunately, the shared mailbox was not activated until mid-December 2023, as evidenced by NHSmail ticket number INC40336913. Attached are some screenshot of emails ref to NHSmail setup.

- 2.3 Furthermore, the previous owners, Lloyds Pharmacy, did not provide any documentation indicating that such a directive had been issued. Even if they had, it appears that NHSE failed to update their records and notify us accordingly. The direction of the letter seems to be based on the old ODS code, as per our findings (the local area opening times schedule states Lloyds Pharmacy FCE24).
- 2.4 It is important to note that there has been an ODS code change, and therefore any liabilities for stipulations made should be attributed to the previous owner.
- 2.5 Additionally, please be informed that NHSmail was not activated until mid-December. This was beyond our control, as the NHSmail service encountered some difficulties during the ODS code transfer process.
- 2.6 We kindly request your understanding in this matter and assure you that we are committed to adhering to all relevant regulations and guidelines.
- 2.7 Thank you for your attention to this matter.”

3 Summary of Representations

This is a summary of representations received on the appeal.

- 3.1 The Appellant provided information regarding its opening hours as follows:

3.1.1 Core opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
08:30-12:00	08:30-12:00	08:30-12:00	08:30-12:00	08:30-12:00	09:00-13:00	Closed	40 hours
15:00-18:30	15:00-18:30	15:00-18:30	15:00-18:30	15:00-18:30			

3.1.2 Total opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
08:30-18:30	08:30-18:30	08:30-18:30	08:30-18:30	08:30-18:30	Closed	Closed	50 hours

3.2 THE COMMISSIONER

- 3.2.1 “Following the assessment of the rota for the Loughborough area and engagement with the ICB and LPC a proposal to direct letter was initially sent to Lloyds Pharmacy on 21 September 2023, representations against this proposal were not received and therefore a direction letter was sent on 24 October 2023.
- 3.2.2 The pharmacy cited the fact that Lloyds Pharmacy underwent a change of ownership to Pinfold Pharmacy with effect from 26 October 2023. Once the East Midlands Primary Care Team are notified of a change of ownership, we provide the contractor with an email informing them of their obligations with regard to being a new pharmacy, this includes completing the Digital Security

and Protection Toolkit which will then allow the pharmacy to apply for an NHS Net account.

- 3.2.3 Schedule 4, part 3, paragraph 29C(1) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#) an NHS pharmacist must ensure that pharmacy staff at the pharmacy premises (including locums) have access to, and are able to send and receive NHS mail from, a premises specific NHS mail account.
- 3.2.4 The East Midlands Primary Care Team have reviewed the toolkit history for this pharmacy and they did not complete the toolkit until June 2024 Organisation Search ([dsptoolkit.nhs.uk](#)) and therefore would not have been eligible for an NHS Net account. This would have accounted for the delay in the pharmacy getting an NHS Mail account.
- 3.2.5 The new pharmacy owners state that the ODS code changed, and there were problems with setting up because of the new ODS code by NHS Mail Services and therefore any liabilities to undertake the bank holiday opening was with the previous owners, even though the direction was not transferred to the new owners this should have been part of the due diligence undertaken by Pinfold Pharmacy to establish if any direction was pending when they took over the premises from Lloyds Pharmacy, this would be part of the change of ownership application that they are required to provide the same services as the previous owner.
- 3.2.6 The process that the East Midlands primary care team follow for directing for all bank holidays on behalf of Leicester, Leicestershire & Rutland ICB is as follows, the Bank Holiday rota is shared on a fair share basis.
- 3.2.7 I would like to take this opportunity to respond to any further representations provided by Pinfold Pharmacy, 26 Pinfold Gate, Loughborough, Leicester, LE11 1BE."

4 Observations

4.1 THE APPELLANT

- 4.1.1 "Thank you for your email. After reviewing the information provided by East Midlands Primary Care Team, I have identified some inaccuracies.
- 4.1.2 Regarding the statement:
- 4.1.3 "The East Midlands Primary Care Team have reviewed the toolkit history for this pharmacy and they did not complete the toolkit until June 2024 Organisation Search ([dsptoolkit.nhs.uk](#)) and therefore would not have been eligible for an NHS Net account. This would have accounted for the delay in the pharmacy getting an NHS Mail account."
- 4.1.4 Our DSP Toolkit was actually completed on 11/12/2023, as demonstrated by the attached emails and the timeline outlined below:
- 4.1.5 27/11/2023: Toolkit creation
- 4.1.6 27/11/2023: Confirmation that the DSP Toolkit was added
- 4.1.7 05/12/2023: Confirmation to copy our HO Toolkit over to FVT74
- 4.1.8 11/12/2023: Confirmation that our Toolkit was applied

- 4.1.9 This clearly shows that our DSP Toolkit was cleared and uploaded on 11/12/2023, not June 2024, as stated. Additionally, our NHS Mail account was active around 21/12/2023 and had sent our first email on the 22/12/23. Therefore, any delay in setting up our NHS Mail account cannot be attributed to the Toolkit completion in June 2024, as claimed.
- 4.1.10 We adhered to NHSE guidance when setting up our NHS Mail. The initial issue arose when Lloyds changed the ODS code shortly before we began the process—no NHS Mail account had been set up under the new ODS code FVT74. Subsequently, we encountered several issues while setting up the account, which are outlined in the attached emails and timeline.
- 4.1.11 Furthermore, East Midlands Primary Care Team have mentioned:
- 4.1.12 "The pharmacy cited the fact that Lloyds Pharmacy underwent a change of ownership to Pinfold Pharmacy with effect from 26th October 2023. Once the East Midlands Primary Care Team are notified of a change of ownership, we provide the contractor with an email informing them of their obligations with regard to being a new pharmacy, this includes completing the Digital Security and Protection Toolkit which will then allow the pharmacy to apply for an NHS Net account."
- 4.1.13 Could you kindly confirm the email address this communication was sent to?
- 4.1.14 We are an independent community pharmacy group with several branches, committed to providing a service to our patients. Had we been aware of the Direction to Open, sent under the correct name and ODS code, we would have taken the necessary actions to ensure we were open. We had received Easter Sunday Provision to open request in March on our shared mailbox – to which we had also volunteered to open, however we were informed that cover had been found.
- 4.1.15 NHSE are expected to maintain up-to-date records of pharmacies in the region. The schedule of pharmacies states Lloyds Pharmacy with the ODS code FCE24. If any emails had been sent to our NHSmail box - up until 22/12/23 there would have been a bounce back as it wasn't active. All these points should be taken into consideration."

5 Consideration

- 5.1 Under Regulation 71(1) "Breaches of terms of service: breach notices" of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"), a Breach Notice may be issued:
- 71. (1) Where an NHS chemist (C) breaches a term of service and the breach is not capable of remedy, NHS England may by a notice ("a breach notice") require C not to repeat the breach.*
- 5.2 I note that in the Regulations an NHS Chemist means "*an NHS appliance contractor or an NHS pharmacist*". An NHS pharmacist is defined as "*a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a);*". Regulation 10(2)(a) states:
- 10(2) "Those lists (which are pharmaceutical lists) are*
- (a) a list of persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs;"*
- 5.3 The Regulations contain no definition as to what constitutes a breach of terms of service which is not capable of remedy.

- 5.4 I note that the pharmacy is included on the pharmaceutical list and that there is no dispute between the parties with regard to this.
- 5.5 I note that the Breach Notice was issued pursuant to Regulation 71(1) and is compliant with the requirements of a breach notice as it includes the nature of the breach and an explanation of the Appellant's right of appeal under Regulation 77(1)(c).
- 5.6 The Breach Notice states:
- 5.6.1 *"Following an assessment of the need for the provision of pharmaceutical services on Tuesday 26 December 2023, and taking into account which pharmacies would be open on that day, Leicester, Leicestershire and Rutland Integrated Care Board (ICB) directed LP SD Fifty Eight Limited (the contractor) to open the above-mentioned pharmacy between 14:00 and 16:00hrs on Tuesday 26 December 2023. No appeal was made against the decision to issue the direction.*
- 5.6.2 *Upon noting that no claim had been made by the contractor, the ICB contacted the contractor to establish why this was the case. A copy of the responsible pharmacist log or other assurance was requested for that day which would evidence when the pharmacy opened. This was not received by the ICB. A remedial notice was also issued so that the pharmacy could send in assurance of opening on the directed day, but this was not provided."*
- 5.7 I note that there is no suggestion that the Appellant did not receive the Commissioner's attempts to contact it, or that it did not receive the Remedial Notice (of which I have not been provided with a copy). I am therefore of the view that the Appellant had the opportunity to enter into local dispute resolution with the Commissioner but did not do so. Given that there is no dispute raised by either party that the local dispute resolution process has not been exhausted, I am content that I can deal with this matter.
- 5.8 I note that the Appellant seeks to appeal against the decision of the Commissioner to issue the Breach Notice for its failure to open for directed hours between 14:00 and 16:00 on Tuesday 26 December 2023.
- 5.9 The Breach Notice alleges a breach of paragraph 23(1)(c) of Schedule 4 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations") for *"failure to ensure the pharmacy premises were open for the provision of pharmaceutical services between 14:00 and 16:00hrs on Tuesday 26 December 2023"*.
- 5.10 Paragraph 23(1)(c) states:
- 5.10.1 **23. Pharmacy opening hours: general**
- (1) Subject to paragraph 23A, an NHS pharmacist (P) must ensure that pharmaceutical services are provided at P's pharmacy premises—*
- ...*
- (c) if NHS England or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 40 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;*
- 5.11 I further note that paragraphs 23(1)(d) and (e) state:
- 5.11.1 *(d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided*

at the premises for more than 40 hours per week, and at set times and on set days, at the times and on the days so set, subject to any variation in respect of a rest break in accordance with sub-paragraph (7)(bd); or

(e) if NHS England or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 40 hours each week, but only on set times and on set days as regards the additional opening hours, or the core opening hours where paragraph 26(4A) applied to the issuing of the direction—

(i) for the total number of hours each week required by virtue of that direction, and

(ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction, subject to any variation in respect of a rest break in accordance with sub-paragraph (7)(bd),

but NHS England may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension.

- 5.12 The parties were invited to provide comments regarding the above Regulations, but I note that none were received.
- 5.13 There is no dispute that the Appellant did not open for the directed hours on 26 December 2023. The Appellant argues that it was not aware of the direction due to a series of circumstances described in its appeal and observations.
- 5.14 The Commissioner states in its representations that *"Following the assessment of the rota for the Loughborough area and engagement with the ICB and LPC a proposal to direct letter was initially sent to Lloyds Pharmacy on 21 September 2023, representations against this proposal were not received and therefore a direction letter was sent on 24 October 2023."*
- 5.15 I note that the Appellant underwent a change of ownership on 26 October 2023 and states that the previous owners, Lloyds Pharmacy, did not inform it of the direction to open on 26 December 2023. The Appellant further states that *"...it appears that NHSE failed to update their records and notify us accordingly. The direction of the letter seems to be based on the old ODS code, as per our findings (the local area opening times schedule states Lloyds Pharmacy FCE24)"* and *"It is important to note that there has been an ODS code change, and therefore any liabilities for stipulations made should be attributed to the previous owner."*
- 5.16 I note that the direction letter was sent on 24 October 2023, based on the information provided by the parties, I note that, at that time, the pharmacy was still under the ownership of Lloyds Pharmacy; the Appellant only took ownership of Pinfold Pharmacy on 26 October 2023. I note that the Appellant states that the Commissioner *"failed to update their records and notify [them]"*. I do not consider this to be the correct construction of the facts. As per the extract above, paragraph 23(1)(d) of the Regulations uses the phrase *"premises"*, therefore, the direction was issued in relation to the premises. The Appellant was not in ownership of the pharmacy at that relevant time. The Commissioner's records correctly indicated that Lloyds Pharmacy should have been notified. I consider that there was no "failure" when the Commissioner notified Lloyds Pharmacy and issued the letter to them. I have not been pointed to any requirement in the Regulations for the Commissioner to notify the Appellant.

- 5.17 The Appellant then states that its NHSmail account was not activated until mid-December and that it was beyond the Appellant's control "*as the NHSmail service encountered some difficulties during the ODS code transfer process.*"
- 5.18 In response to the appeal, the Commissioner states that "*Once the East Midlands Primary Care Team are notified of a change of ownership, we provide the contractor with an email informing them of their obligations with regard to being a new pharmacy, this includes completing the Digital Security and Protection Toolkit which will then allow the pharmacy to apply for an NHS Net account.*" I note that the Appellant has responded to this by querying the email address to which this was sent. I have not been provided with a copy of the email.
- 5.19 The Commissioner further states that "*The East Midlands Primary Care Team have reviewed the toolkit history for this pharmacy and they did not complete the toolkit until June 2024 Organisation Search (dsptoolkit.nhs.uk) and therefore would not have been eligible for an NHS Net account. This would have accounted for the delay in the pharmacy getting an NHS Mail account.*"
- 5.20 The Appellant responds that its DSP Toolkit was completed on 11 December 2023 and has provided an email dated 11 December 2023 from the NHS Service Desk confirming that "*The 22/23 Standards Met assessment for BELGRAVE PHARMACY (FJF59) has been applied to FVT74 for 22/23.*" which it states is confirmation that the DSP Toolkit was completed. I note the Appellant further states that its NHSmail account was "*active around 21/12/2023*" and that it had sent its first email on 22 December 2023.
- 5.21 Whilst I note the difficulties the Appellant appears to have experienced in setting up the NHSmail account, it is not clear whether access to this earlier would have allowed it to view historic emails sent to the previous owner, including those regarding the direction. I note in any case that the account was active before the date of the directed hours. Therefore, if the account did allow retrospective access, I consider that the Appellant would have been able to view the direction letter at that point. As this does not appear to be the case, I consider it unlikely that earlier access to the NHSmail account would have provided them with any additional notification of the direction letter. Based on this conclusion I consider that even had the Appellant had access to NHSmail on the date that it took ownership (26 October 2023), it would have been in no better position than it was when its NHSmail account actually became active in December. As such I consider that the Appellant's ability to access their NHSmail account had no bearing on whether they received the direction and were consequently able to act on it. I do not consider it a mitigating factor as to why it did not open on 26 December 2023.
- 5.22 I note the Commissioner's view that "*even though the direction was not transferred to the new owners this should have been part of the due diligence undertaken by Pinfold Pharmacy to establish if any direction was pending when they took over the premises from Lloyds Pharmacy, this would be part of the change of ownership application that they are required to provide the same services as the previous owner.*"
- 5.23 Regulation 26(1) regarding Change of ownership applications states:
- 5.23.1 26.—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application from a person who is not included in a pharmaceutical list for inclusion in the list, or from a person included in a pharmaceutical list for inclusion in that list also in respect of other premises than those already listed in relation to that person, if—
- ...
- (b) X is proposing to carry on at the listed chemist premises, in place of Y, the business in the course of which Y is providing pharmaceutical services at those premises;

(c) X is undertaking to provide the same pharmaceutical services as those that Y is providing; and ...

5.24 I consider that it would have been helpful, given that only 2 days had passed between the direction being issued and the change of ownership taking place, if the Commissioner had made an effort to contact the Appellant in order to confirm the direction. However, I have not been made aware of any legal obligation on the Commissioner to do so. As such I am of the view that the onus was on the Appellant to ensure that services were provided in accordance with those hours accepted and provided by the previous owner, including any directions to open the premises for additional hours.

5.25 I note that paragraph 23(12) states:

5.25.1 *(12) For the purposes of calculating the number of hours that pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week.*

5.26 I have not been provided with any other reason why the Appellant was unable to open on 26 December 2023. I must note that the Appellant has indicated that had it been aware of the direction, it would have opened and it has volunteered to open on Easter Sunday which is commendable. Despite this and given that the two directed hours were additional to the Appellant's usual 40 core hours of opening, I am of the view that the Appellant's failure to open between 14:00 and 16:00 on 26 December 2023 is a breach of paragraph 23(1)(e).

6 Decision

6.1 I am of the view that under NHS Resolution's powers, as set out in paragraph 9(5) of Schedule 3 to the Regulations, I may either confirm the decision of the Commissioner or substitute for that decision any decision that the Commissioner could have taken when it took that decision.

6.2 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations I substitute the decision of the Commissioner to issue the Breach Notice with a decision to issue a breach notice stating that the failure to open for the directed hours on 26 December 2023 is a breach of paragraph 23(1)(e).

**Head of Appeals
NHS Resolution**