

21 December 2023

REF: SHA/26077

**APPEAL AGAINST NHS LEICESTER, LEICESTERSHIRE
AND RUTLAND ICB DECISION REGARDING A BREACH
NOTICE AT MEDICURE PHARMACY, 107 TURNBULL
DRIVE, LEICESTER, LEICESTERSHIRE, LE3 2JW**

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Tel: 0203 928 2000
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1 Outcome

- 1.1 Pursuant to paragraph 9(5)(b) of Schedule 3 to the Regulations, I substitute the decision of the Commissioner to issue the Breach Notice with the decision to issue a remedial notice with the same wording except for the changes below:
 - 1.1.1 substitute all references to “breach notice” and “regulation 71” with reference to “remedial notice” and “regulation 70”;
 - 1.1.2 substitute the requirement to not repeat the breach with the requirement to remedy the breach within the notice period; and
 - 1.1.3 the Commissioner must indicate to the Appellant how and in what format the questionnaire should be completed. The timescale for remedy will be 30 days from the date of that communication.

A copy of this decision is being sent to:

Medicure Pharmacy
Leicester, Leicestershire and Rutland ICB

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1 The Breach Notice

A Breach Notice dated 21 August 2023 was sent to Medicure Pharmacy in respect of Medicure Pharmacy, 107 Turnbull Drive, Leicester, Leicestershire, LE3 2JW.

- 1.1 “Please see the enclosed breach notice which has been issued to the above named pharmacy.
- 1.2 Please be aware that failure to comply with breach notices may result in the implementation of formal contract sanctions, which could include the withholding of all or part of the remuneration payable to the pharmacy or termination of a contract.”

Breach Notice

- 1.3 “Name of contractor: Medicure Pharmacy
- 1.4 Address of premises: 107 Turnbull Drive, Leicester, Leicestershire, LE3 2JW
- 1.5 Date of inclusion in the pharmaceutical list for the area of Leicester City Health and Wellbeing Board: 1 November 2007
- 1.6 This is a breach notice issued under regulation 71 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended.
- 1.7 Nature of the breach
- 1.8 Schedule 4, Part 4, Paragraph 35(5) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended states that a pharmacy at the request of the commissioner or a person authorised in writing by the commissioner by means of an electronic communication, a duly completed questionnaire, which is;
 - 1.8.1 (a) in a format approved by the commissioner; and
 - 1.8.2 (b) for the purpose of enabling the commissioner or a person authorised by NHS the commissioner, to determine whether or when it is necessary or expedient for a person authorised in writing by the commissioner to undertake an inspection of the pharmacy’s premises.
- 1.9 As a result of NHS regulations introduced at the end of 2020, completion of Community Pharmacy Assurance Framework is now a requirement of the Terms of Service. Therefore, contractors must complete the screening questionnaire and, if required, the full CPAF questionnaire.

- 1.10 In order to demonstrate compliance with the community pharmacy assurance framework, the commissioner and NHS BSA on behalf of the commissioner have requested completion of the questionnaire on a number of occasions. However, the pharmacy has failed to submit the screening questionnaire and has provided no valid reason why.
- 1.11 The commissioner have therefore found Medicure Pharmacy, 107 Turnbull Drive, Leicester, Leicestershire, LE3 2JW to be in breach under Regulation 71, in respect of the breach of; Schedule 4, Part 4, Paragraph 35(5) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended. You are required to not repeat the breach again. The pharmacy has now been put forward to complete the full questionnaire for 2023-24. The NHS BSA will send an invite to the pharmacy when this is available to complete.
- 1.12 You have a right of appeal to the Secretary of State against the issuing of this breach. Should you choose to appeal then you should send a concise and reasoned statement of the grounds for you appeal within 30 days of the date of this notice to nhsr.appeals@nhs.net or: Primary Care Appeals, Case Manager, NHS Resolution, 8th Floor 10 South Colonnade, Canary Wharf, London, E14 4PU
- 1.13 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 pharmaceutical list under regulation 73 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended."

2 The Appeal

In an email dated 10 September 2023 and addressed to NHS East Midlands, Medicure Pharmacy appealed against the Breach Notice. NHS Resolution received confirmation from Medicure Pharmacy that the appeal was misaddressed, and the intention was to appeal the Breach Notice to NHS Resolution, not NHS East Midlands. The grounds of appeal are:

- 2.1 "Appeal Statement
- 2.2 Firstly, thank you for getting to me. I now realised [sic] that the deadline was end of July 2023 for the CPAF even though numerous emails were sent out prior to the deadline which I had not read. I had been very busy taking time off work when ever possible to go to Portugal to support my wife as my mother-in-law has not been well with severe dementia which has devastated the family and is very difficult for us. There was too much going on at work too like most of us going through. Lack of stock etc, staffing issues and not only looking after the pharmacy business but also young children whilst my wife was with her mum in Portugal or me accompanying her. This year has been very though [sic] for me and my family.
- 2.3 I was aware that the CPAF questionnaire needed to be done but thought that I have till end of August 2023 to submit as I had submitted last years questionnaire in August.
- 2.4 I am very annoyed with myself as due to juggling between Portugal and England I did not read my emails and if I had done so I would done [sic] the CPAF Questionnaire so as [sic] it only requires answering 10 questions. Due to all this I have now received a breach notice which I am upset about and would want to appeal with the above reason.
- 2.5 I would appreciate if I would be allowed to do the CPAF questionnaire that was due end of July 2023 by removing the breach notice."

3 Summary of Representations

This is a summary of representations received on the appeal.

- 3.1 NHS EAST MIDLANDS PRIMARY CARE TEAM (ON BEHALF OF THE ICB) (“the Commissioner”)
- 3.1.1 “Schedule 4, Part 4, Paragraph 35 (5) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended states that a pharmacy must at the request of the commissioner or a person authorised by the commissioner to make the request, send to the commissioner or that person by means of an electronic communication, a duly completed questionnaire.
- 3.1.2 Community pharmacies are governed by The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and the Community Pharmacy Contractual Framework (CPCF). Part of the CPCF is the Community Pharmacy Assurance Framework (CPAF).
- 3.1.3 The East Midlands Primary Care Team on behalf of the 5 ICBs use the CPAF to monitor community pharmacy contractors’ compliance with the terms of the Community Pharmacy Contractual Framework (CPCF).
- 3.1.4 The CPAF consists of all pharmacy contractors being requested to complete a short screening questionnaire, which consists of 10 questions for which the pharmacy contractor is asked to self-assess against certain aspects of their terms of service. When answering the questions contractors should select the statements that most closely match what happens in their pharmacy.
- 3.1.5 Historically the completion of the CPAF was not a compulsory function however, as a result of NHS regulations introduced at the end of 2020, completion of CPAF is now a requirement of the Terms of Service. Therefore, contractors must complete the screening questionnaire within the required time period each year and, if required, the full CPAF questionnaire. The screening questionnaire ran from the 03 July 2023 until Midnight on 30 July 2023.
- 3.1.6 The commissioner and the NHS BSA on behalf of the commissioner, have contacted the pharmacy on a number of occasions, each of the communications informed the pharmacy that the questionnaire was now a regulatory requirement and that failure to complete the questionnaire would result in a referral to the Pharmaceutical Services Regulations Committee and that this referral may result in the issue of a breach notice.
- 3.1.7 Additional reminders are also posted on other mediums such as community pharmacy England website [2023/24 Community Pharmacy Assurance Framework \(CPAF\) screening questionnaire has opened - Community Pharmacy England \(cpe.org.uk\)](#) and the NHS BSA website [Community Pharmacy Assurance Framework \(CPAF\) | NHSBSA](#) . Each of these websites detailed how the questionnaire could be completed and the dates in which it should have been completed.
- 3.1.8 The team also contacted the pharmacy on 11 August 2023 giving the pharmacy an opportunity to provide any mitigating circumstances as to why they failed to complete the questionnaire.
- 3.1.9 An email from the pharmacy was received on 22 August 2023 explaining that the pharmacy thought that the questionnaire did not need to be completed until the end of August. The team do sympathise with the situation explained in the email and the appeal; however, the questionnaire has now been compulsory since 2021 and forms part of the pharmaceutical regulations and the terms of service. With regard to the problems mentioned within the appeal including staff issues, the pharmacy could have contacted their LPC representative or made contact with any of the East Midlands Primary Care Team to gain support.

- 3.1.10 I would like to take this opportunity to respond to any further representations provided by Medicure Pharmacy, 107 Turnbull Drive, Leicester, LE3 2JW."

4 Observations

This is a summary of observations received on the appeal.

4.1 MEDICURE PHARMACY

- 4.1.1 "I write in relation to the letter dated 2nd October 2023 to provide detailed information on the reason why I was unable to submit the CPAF in July 2023.

- 4.1.2 I am grateful, you have provided a brief copy of my email response dated 14 August 2023. In my response I stated there was several reasons why I was unable to submit the CPAF. I will speak about each reason in further detail.

Staffing issues:

- 4.1.3 In my initial email I had written lack of stock etc, staffing issues without providing a full explanation.

- 4.1.4 The reason behind the lack of stock was that pharmacies are going through shortages of medications in which a number of suppliers do not have the medications available and that further the suppliers charge above the drug tariff and concession prices for the medication agreed by the NHS. Unfortunately, this takes up a lot of our time in sourcing the medication from different suppliers and additionally if there are any concerns, we call the GPs to seek an alternative medication to ensure the patient gets their required medication.

- 4.1.5 I can confirm that the only staff issue during the period of April 2023 to July 2023 involved my wife, who is a pharmacy dispenser at the pharmacy. Sadly, she had to take time off work due to personal family reasons. My wife, whose parents reside in Portugal were unwell (see attachment), especially her mother who has been diagnosed with severe dementia and so she had to travel to Portugal to assist her in this difficult time. Unfortunately, this meant that the pharmacy was without one dispenser. I, as the owner and pharmacist had to step in and take over further responsibilities in the pharmacy to accommodate my wife's absence. This also meant that the whole team were having to work around to support the business and patients.

- 4.1.6 Furthermore, I would like to make it clear that in my appeal I had stated that 'I was aware that the CPAF questionnaire needed to be done but thought that I have till end of August 2023 to submit as I had submitted last year's questionnaire in August' and not as stated in the letter dated 2nd October 2023 that 'the pharmacy thought that the questionnaire did not need to be completed until the end of August 2023.

- 4.1.7 I had also not read the emails in my busy schedule, the emails had moved down, as more emails were coming through. This was for the fact that the more emails had dropped in the mail box and any recent emails had moved up so the emails were not seen.

- 4.1.8 Nevertheless, I can confirm that this was the first time, and the only staff issue I have encountered at the pharmacy. However, I have taken on board the comments from [LD's] email dated 02/10/2023 that contacting either my LPC representative or any of the East Midland Primary care team to gain support if there is a staffing issue at the pharmacy.

Mother-in-law - unwell with Demetia.

- 4.1.9 As explained in my initial email to you, my mother-in-law suffers from Dementia and had become seriously unwell. My wife, who is the dispenser had to travel to Portugal to look after her mother. I enclose a copy of a letter from my mother in laws doctor for further consideration.

Father-in-law - unwell with heart attack this year.

- 4.1.10 Unfortunately, I had forgotten to mention in my appeal that my wife's father had suffered from a heart attack this year and she had to travel to Portugal to attend to him too. I enclose a copy of a letter from my father in laws doctor for further consideration.
- 4.1.11 Unfortunately, both the incidents above have had an immense impact on both me and my wife. I have had to take on further responsibilities at the pharmacy and in my personal life by carrying out house chores and looking after and collecting my children from school, role that my wife normally undertakes.
- 4.1.12 I hope the above provides enough information for my appeal on this matter but if further documentation is required, please let me know and I would be happy to provide.
- 4.1.13 Furthermore, the documents provided from the doctor's are written in Portuguese and I am in the process of getting these documents translated. Given the deadline, I thought it would be best for me to forward you the documents now rather than later. Once the documents are translated, I will forward a copy to you. I hope you find this acceptable.
- 4.1.14 I would also like to take this opportunity to confirm that I have filled out the questionnaire every year without fail but unfortunately given the circumstances this year I was not able to meet the deadline. I have taken into account this incident and apologise that I have not met the requirement to submit the CPAF questionnaire on time and going forward I have learnt from this and have made sure I have placed alerts to ensure I can meet the deadline for CPAF without fail.
- 4.1.15 I hope you can take my concerns into account with evidence provided when finalising your decision on my appeal.
- 4.1.16 I would like to thank you in advance for your understanding and I look forward to hearing from you soon."

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, the NHSCB may by a notice ("a breach notice") require C not to repeat the breach.

- 5.2 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 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 "...the Commissioner and NHS BSA on behalf of the commissioner have requested completion of the questionnaire on a number of occasions. However, the pharmacy has failed to submit the screening questionnaire and has provided no valid reason why." Although I have not been provided with copies of the communication (whether this was via letter or email) sent 'on a number of occasions', the Appellant is in agreement that numerous emails were sent from the Commissioner in relation to the CPAF screening questionnaire and its deadline for completion.
- 5.7 I am of the view that the Appellant had the opportunity to enter into local dispute resolution with the Commissioner but did not do so. There is no dispute raised by either party that the local dispute resolution process has not been exhausted. Given that both parties do not dispute that local dispute resolution has been exhausted I am content that I can deal with this matter.
- 5.8 The Appellant seeks to appeal against the decision of the Commissioner to issue the Breach Notice for its failure to complete and submit the CPAF screening questionnaire.
- 5.9 I note that "Inspections and access to information" is found in Schedule 4, Part 4, 'Other Terms of Service' under Paragraph 35 and states:

35. Inspections and access to information

(1) An NHS pharmacist (P) must allow persons authorised in writing by the NHSCB to enter and inspect P's pharmacy premises at any reasonable time, for the purposes of—

(a) ascertaining whether or not P is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing—

(i) the provision made by P, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and

(ii) the management by P of the pharmaceutical services P provides, where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) reasonable notice of the intended entry has been given;

(b) the Local Pharmaceutical Committee for the area where the pharmacy premises are situated have been invited to be present at the inspection, where this is requested by P;

(c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and

(d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) P must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

(4) P must, at the request of the NHSCB, send to the NHSCB by means of an electronic communication of the type specified in the request any information to which a person authorised in writing by the NHSCB would have access during an inspection of P's pharmacy premises pursuant to sub-paragraph (1), if—

(a) P has that information in a form which means it may be sent by that form of electronic communication; or

(b) it is reasonable for the NHSCB to request that P convert that information into a form which means that it may be sent by that form of electronic communication (and the NHSCB does so request)

(5) P must, at the request of NHSCB or a person authorised in writing by the NHSCB to make the request, send to the NHSCB or that person by means of an electronic communication, a duly completed questionnaire, which is –

(a) in a format approved by the NHSCB; and

(b) for the purpose of enabling NHSCB, or a person authorised in writing by the NHSCB to determine whether or when it is necessary or expedient for a person authorised in writing by the NHSCB to undertake an inspection of P's premises pursuant to sub-paragraph (1).

(6) Before information is requested pursuant to sub-paragraph (5), the NHSCB must consult the person who is, for the time being, the person consulted under section 165(1)(a) of the 2006 Act, in respect of pharmaceutical remuneration of NHS pharmacists on the terms of the request.

- 5.10 I note the Commissioner's comment that the screening questionnaire was sent to all pharmacies for completion, and this ran from 3 July 2023 until midnight on 30 July 2023. I further note that the Appellant had been contacted by the Commissioner on 11 August 2023 to query the uncompleted questionnaire and that the Appellant replied to this email on 22 August 2023 explaining the unfortunate family circumstances which had led to the deadline being missed.
- 5.11 I note that the Appellant has not disputed that the original request for the screening questionnaire to be completed arrived at the premises specific email address and simply states that the "emails were not read". I am unable to comment on whether the CPAF questionnaire for previous years was completed in August as am simply looking at the circumstances surrounding the 2022 – 2023 screening questionnaire.
- 5.12 For reasons given above, I conclude that by failure to complete the CPAF screening questionnaire when requested to do so, the Appellant was in breach of paragraph 35(5), Schedule 4 of the Regulations.
- 5.13 I next consider whether the failure to complete the CPAF screening questionnaire is a breach which is capable of remedy. As noted in paragraph 5.3 above, the Regulations do not contain a definition as to what constitutes a breach of terms of service which is

or is not capable of remedy. A common-sense interpretation is that a breach is unable to be rectified.

- 5.14 The Appellant was required to complete the screening questionnaire. Completion of the questionnaire even if not within the time period given would have remedied or rectified the breach. Further I note there is no timescale set out in this provision of the Regulations to submit the screening questionnaire. If there had been, the breach could not have been remedied. I note the comment by the Appellant in its appeal that it “*would appreciate if [the Applicant] would be allowed to do the CPAF questionnaire that was due end of July 2023*” which implies that the Appellant is willing to complete the questionnaire if the ability to do so was provided to it.
- 5.15 Under Regulation 70 of the Regulations, a remedial notice may be issued:
- “70(1) Where an NHS chemist (C) breaches a term of service and the breach is capable of remedy, the NHSCB may by a notice (“a remedial notice”) require C to remedy the breach.”*
- 5.16 I consider that both remedial and breach notices carry the same weight in terms of severity of possible consequence, with the difference being that a remedial notice requires the remedy of the breach, and the breach notice requires an NHS chemist to not repeat the breach. As the Appellant has failed to complete the questionnaire within the timescale set by the Commissioner, it is entirely appropriate to require the Appellant to remedy the breach.
- 5.17 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.
- 5.18 As a result of the comments I make above, I am of the view that:
- 5.18.1 the Appellant did not complete and submit the CPAF screening questionnaire within the timeframe set by the Commissioner; and
- 5.18.2 such action constitutes a breach of the Appellant’s terms of service by virtue of Regulation 35, which is capable of remedy.
- 5.19 As I am substituting the Commissioner’s decision to issue the Breach Notice with a decision to issue a remedial notice, I determine that the Appellant is required to remedy the breach by providing the information requested (and therefore completing the questionnaire). I note that the Appellant has indicated that it is willing to complete the questionnaire. I consider that the Appellant should therefore be able to provide this information. In this regard, I note that Regulation 70(3) requires the notice period for remedying the breach to be not less than 30 days. The Appellant is therefore required to remedy the breach within 30 days of the date on which the Commissioner indicates to the Appellant that the remedial action should be undertaken.
- 5.20 To be clear, the Commissioner must indicate to the Appellant how and in what format the questionnaire should be completed. The timescale for remedy will be 30 days from the date of that communication.

6 Decision

- 6.1 Pursuant to paragraph 9(5)(b) of Schedule 3 to the Regulations, I substitute the decision of the Commissioner to issue the Breach Notice with the decision to issue a remedial notice with the same wording except for the changes below:
- 6.1.1 substitute all references to “breach notice” and “regulation 71” with reference to “remedial notice” and “regulation 70”;

- 6.1.2 substitute the requirement to not repeat the breach with the requirement to remedy the breach within the notice period; and
- 6.1.3 the Commissioner must indicate to the Appellant how and in what format the questionnaire should be completed. The timescale for remedy will be 30 days from the date of that communication.

**Head of Appeals
NHS Resolution**