

17 May 2024

REF: SHA/26176

APPEAL AGAINST NOTTINGHAM AND NOTTINGHAMSHIRE ICB DECISION REGARDING A BREACH NOTICE AT MANSFIELD WOODHOUSE PHARMACY, 12 HIGH STREET, MANSFIELD WOODHOUSE, NOTTINGHAMSHIRE NG19 8AN

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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.
- 1.2 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:

Mansfield Woodhouse Pharmacy
Nottingham and Nottinghamshire ICB

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1 The Breach Notice

A Breach Notice dated 23 February 2024 was sent to Mansfield Woodhouse Pharmacy (“the Appellant”) in respect of 12 High Street, Mansfield Woodhouse, Nottinghamshire NG19 8AN. The Breach Notice stated:

1.1 “This is a Breach notice issued under regulation 71 of the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.2 Nature of the breach

1.3 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 East Midlands Primary Care Team (on behalf of Nottingham and Nottinghamshire Integrated Care Board) or person authorised in writing by of The East Midlands Primary Care Team (on behalf of Nottingham and Nottinghamshire Integrated Care Board) to make the request, send to The East Midlands Primary Care Team or that person by means of an electronic communication, a duly completed questionnaire.

1.4 In order to demonstrate compliance with the community pharmacy assurance framework, of The East Midlands Primary Care Team (on behalf of Nottingham and Nottinghamshire Integrated Care Board) and NHS BSA on behalf of The East Midlands Primary Care Team (on behalf of Nottingham and Nottinghamshire Integrated Care Board) requested completion of the full questionnaire on a number of occasions (06 November 2023, 13 November 2023, 20 November 2023, 27 November 2023, 28 November 2023, 04 December 2023 and 07 December 2023). However, the pharmacy failed to submit the full questionnaire by the deadline and has provided no valid reason why. The questionnaire closed on 17 December 2023 therefore the breach of the terms of service is incapable of remedy.

1.5 The East Midlands Primary Care Team (on behalf of Nottingham and Nottinghamshire Integrated Care Board) therefore referred this matter of non-compliance to the Pharmaceutical Services Regulations Committee on 16 January 2024. The PSRC found the pharmacy to be in breach of the terms of service for failure to provide a duly completed questionnaire when requested and as the breach was incapable of remedy then the decision was made to issue a breach notice.

1.6 The East Midlands Primary Care Team (on behalf of Nottingham and Nottinghamshire Integrated Care Board) have therefore found Mansfield Woodhouse Pharmacy, 12 High Street, Mansfield Woodhouse, Nottinghamshire, NG19 8AN 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.

1.7 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:

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

1.8 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 11 March 2024 addressed to NHS Resolution, the Appellant appealed against Nottingham and Nottinghamshire ICB’s decision. The grounds of appeal are:

2.1 “To NHS England Pharmacy Contracts team

2.2 Name of contractor: Mansfield Woodhouse Pharmacy Address of premises:, 12 High Street, Mansfield Woodhouse, Nottinghamshire, NG19 8AN Date of inclusion in the pharmaceutical list for the area of Nottinghamshire County Health and Wellbeing Board: 28 June 2023

2.3 I am writing today to Appeal the breach notice received on the 23rd of Feb 2024.

2.4 I have attached the breach letters received and also the email we sent on the 9th of January explaining the reasons for the missed deadline for the CPAF questionnaire sent by Ivana on the 9th of Jan.

2.5 We have subsequently asked for the CPAF to be sent to us again so we can complete the questionnaire and submit the details required. We have still not received the CPAF questionnaire and would like someone to get in touch with myself from either the NOTTS pharmacy team or NHS England on [telephone number redacted].

2.6 I did speak to someone in early January about the missed deadline and I was told that the questionnaire would be emailed over to us to complete, but this has not happened. If you can kindly reconsider the breach notice on the grounds that we had recently taken over the branch in June and the handover was very turbulent and Lloyds pharmacy did not help us with any information requests we asked from them. Since we took over the issues of communication with the previous owners has been very problematic due to them going into administration.

2.7 We did reply on the 9th of Jan to the missed deadline but we did not get any correspondence to the email.

2.8 We are committed to completing the questionnaire and ensuring full compliance with all regulations.

2.9 We take our contractual obligations very seriously and would like to be compliant asap.

2.10 We appreciate your understanding in this matter, please let us know how we can resolve this matter.

2.11 Please see attached email correspondence from 9th Jan and breach notices attached.”

Email correspondence dated 9 January 2024 from the Appellant to the Commissioner which stated:

- 2.12 “Dear NHS England
- 2.13 Firstly we would like to apologise for the omission of completing the full CPAF survey. We are aware this is a contractual requirement to be actioned. Each store had been notified centrally to action the CPAF. Some branches have had issues logging to access due to being taken over recently and delays in gaining access to a new shared NHSmail box. We have had some ongoing IT issues in our stores due to changes of PMR systems and internet lines. This has led to some delays in response to Questionnaire. We have ensured this has been resolved for our stores in a timely manner.
- 2.14 Each store had planned to complete the CPAF questionnaire. Unfortunately the deadline date was missed off and stores had planned to complete this . When trying to access this they couldn't find the link on MYS.
- 2.15 During the lead up to the busy period of Christmas, stores had seen an increase in footfall and with the workload. Our Patients facing team have also had an increase in COVID and FLU vaccinations along with NHS hypertension service.
- 2.16 We have requested access to shared NHSmail box and individual NHSmails”

3 Summary of Representations

No representations were received by NHS Resolution on the appeal.

4 Consideration

- 4.1 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.

- 4.2 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;”

- 4.3 The Regulations contain no definition as to what constitutes a breach of terms of service which is not capable of remedy.
- 4.4 I note that the pharmacy is included on the pharmaceutical list and that there is no dispute between the parties with regard to this.
- 4.5 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).
- 4.6 The Breach Notice states that the Commissioner and the NHS BSA on behalf of the Commissioner “requested completion of the full questionnaire on a number of occasions (06 November 2023, 13 November 2023, 20 November 2023, 27 November 2023, 28 November 2023,04 December 2023 and 07 December 2023). However, the

pharmacy failed to submit the full questionnaire by the deadline 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 does not dispute that these communications were received.

- 4.7 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.
- 4.8 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.
- 4.9 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.

- 4.10 The Breach Notice states that the Commissioner requested completion of the questionnaire on a number of occasions and further that “*the pharmacy failed to submit the full questionnaire by the deadline and has provided no valid reason why.*”
- 4.11 In its email dated 9 January 2024 addressed to the Commissioner, the Appellant stated that “*each store had planned to complete the CPAF questionnaire. Unfortunately the deadline date was missed off*”. Further it stated that “*some branches have had issues logging to access due to being taken over recently and delays in gaining access to a new shared NHSmail box.*” The Appellant has not disputed that the requests for the questionnaire to be completed arrived at the premises specific email address, but that there were issues logging into the NHSmail box.
- 4.12 I note the Appellant took over the branch in June 2023, some 5 months before the deadline. I am of the view that the responsibility lies with the Appellant to make sure its NHSmail box was accessible, given it is a requirement of its Terms of Service to ensure staff have access to the pharmacy shared NHSmail mailbox.
- 4.13 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.
- 4.14 I next consider whether the failure to complete the CPAF screening questionnaire is a breach which is capable of remedy. As noted in paragraph 4.3 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.
- 4.15 The Breach Notice states that “*as the breach was incapable of remedy then the decision was made to issue a breach notice*” however no further explanation was provided as to why it was incapable of remedy. Furthermore, the Commissioner has not responded to the appeal to make its position clear.
- 4.16 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 in the appeal that the Appellant has asked for the questionnaire to be sent to it again so it can complete it, but that this has not been done.

4.17 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.”

4.18 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.

4.19 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.

4.20 As a result of the comments I make above, I am of the view that:

4.20.1 the Appellant did not complete and submit the CPAF screening questionnaire within the timeframe set by the Commissioner; and

4.20.2 such action constitutes a breach of the Appellant’s terms of service by virtue of Regulation 35, which is capable of remedy.

4.21 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, 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.

4.22 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.

5 Decision

5.1 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.

5.2 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.