

2 April 2025

REF: SHA/26455

**APPEAL AGAINST GREATER MANCHESTER ICB
DECISION REGARDING A BREACH NOTICE AT BOOTS
PHARMACY (FWT50), HALE TOP, CIVIC CENTRE,
WYTHENSHAW, M22 5RN**

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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” with reference to “remedial notice pursuant to Regulation 70”.
 - 1.1.2 Substitute the requirement not to repeat the breach notice with the requirement to remedy the breach within the notice period.
- 1.2 The Commissioner must indicate to the Appellant how and in what format the information should be provided. The timescale to remedy will be 30 days from the date of that communication.

A copy of this decision is being sent to:

Boots UK Ltd (FWT50)
Greater Manchester ICB

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1 The Breach Notice

A Breach Notice dated 10 January 2025 was sent to Boots UK Ltd (“the Appellant”) in respect of Hale Top, Civic Centre, Wythenshaw, M22 5RN.

1.3 “A number of requests have been made to the pharmacy in regards to Patient safety notification for contractors using EMIS PharmOutcomes IT system and the need to review any unactioned messages associated with the national advanced pharmacy services; specifically where an onward referral to the patient’s GP was the outcome.

1.4 An initial email was sent on 17th September 2024 detailing the actions that the pharmacy needed to complete, which included the submission of a locally agreed auditing report as an MS Form.

1.5 This initial email instructed the following actions by the pharmacy:

1.6 **Action for contractors**

1.6.1 *Review and action the queue of notification emails within the PharmOutcomes system for the clinical services delivered by the pharmacy, in order of priority as set out in Annex 1.*

1.6.2 *Follow instructions for manipulating the suppressed post event messages (PEMs) held within PharmOutcomes as set out in the supporting documentation; and follow guidance for sending notifications to a GP practice where suppressed PEMs need to be sent.*

1.6.3 *If there are any concerns about potential patient harm because of delayed notifications following a pharmacy consultation, please report the incident using the ‘Learning From Patient Safety Events’ portal and use the code ‘PharmacyPEM’ for reporting purposes.*

1.6.4 *Pharmacists must consider and fulfil their duty of candour.*

1.6.5 *Return any locally agreed auditing report to confirm completion of actions.*

1.7 An offer was also made of 3 webinars to provide support to the pharmacy on how to complete this form.

- 1.8 The deadline of Monday 30th September 2024 was given for the pharmacy to complete and submit the MS form.
- 1.9 No response was received from the pharmacy by this deadline, therefore further emails were sent and follow up phone calls made by the Programme Team and LPC with a final extension to the deadline given as Tuesday 22nd October 2024.
- 1.10 NHS Greater Manchester to date has received no communication, response or submission of the MS form from the pharmacy therefore, as detailed in the emails, the issue was raised and discussed at Pharmaceutical Services Regulations Committee (PSRC) for Greater Manchester on Thursday 28th November 2024 in relation to the regulation below.
- 1.11 (SCHEDULE 4, PART 4, Paragraph 35 (3) - The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013)

Inspections and access to information

35.—(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.

- 1.12 The PSRC concluded that Boots UK Ltd has failed to action the request of Post Event Messaging (PEM) – Patient Safety Notification for Pharmacies using PharmOutcomes, therefore the PSRC has deemed this a breach of the regulation reference above.
- 1.13 Boots UK Ltd has 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 by email to nhsr.appeals@nhs.net or by post to:
- 1.14 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London. E14 4PU
- 1.15 Please note that should you fail to comply with the requirements of this breach notice NHS Greater Manchester reserves the right to exercise its powers to take further action in relation to Boots UK Ltd 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 January 2025 addressed to NHS Resolution, the Appellant appealed against Greater Manchester ICB’s (“the Commissioner”) decision. The grounds of appeal are:

- 2.1 “I write this email as the store manager for Boots Wythenshawe FWT50, Hale Top, Civic Centre, Wythenshawe, M22 5RN in response to the email received regarding a breach of pharmacy notice - failure to comply with post event messaging using Pharmoutcomes.
- 2.2 We actioned all messages by the initial deadline of 30th September in store – the pharmacist responsible was *[redacted by NHS Resolution]* and we manually sent notifications via post prior to this deadline also. However, the initial direction I forwarded to the pharmacist appears to have been misunderstood and the MS Form was omitted prior to the workload being completed. I am however unable to investigate thoroughly with the pharmacist as she is *[redacted by NHS Resolution]*. absence but I can assure all parties that this work was completed and is reviewed by our relief replacement pharmacist regularly and efficiently here in Wythenshawe. There were and are no concerns about potential harm because of delayed notifications and I have consulted our pharmacists office and PQSM regarding any queries we have regarding this notice. I have returned the locally agreed auditing form and discussed with the RP together with the pharmacy team. My sincerest apologies for the lack of acknowledgement in this matter as I assumed all was submitted and actioned by RP *[redacted by NHS Resolution]*. - I would like to add that the store received no telephone communication re. this matter and this would have prompted a thorough investigation into the matter and prevented this breach notice being issued.
- 2.3 Please may I ask that this appeal is considered given the above actions completed.
- 2.4 I look forward to hearing the outcome.”

3 Summary of Representations

No representation were received by NHS Resolution in response to the appeal.

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, NHS England 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 Commissioner is of the view that as it received no communication, response or submission from the Appellant, the Appellant was in breach of Schedule 4, Part 4, Paragraph 35 (3) of the Regulations, as quoted at paragraph 1.9 above.
- 4.6 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).
- 4.7 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. I note 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.
- 4.8 The Breach Notice states:
- 4.9 *“A number of requests have been made to the pharmacy in regards to Patient safety notification for contractors using EMIS PharmOutcomes IT system and the need to review any unactioned messages associated with the national advanced pharmacy services; specifically where an onward referral to the patient’s GP was the outcome.*
- 4.10 *....Follow instructions for manipulating the suppressed post event messages (PEMs) held within PharmOutcomes as set out in the supporting documentation.”*
- 4.11 The Breach Notice lists a series of five actions as stated at paragraph 1.4.1 to 1.4.5 above.
- 4.12 I note that the Appellant seeks to appeal against the decision of the Commissioner to issue the Breach Notice on the grounds that “We actioned all messages by the initial deadline of 30th September in store – the pharmacist responsible was [redacted by

NHS Resolution] and we manually sent notifications via post prior to this deadline.” Further “However, the initial direction I forwarded to the pharmacist appears to have been misunderstood and the MS Form was omitted prior to the workload being completed. I am however unable to investigate thoroughly with the pharmacist as she is on long term sickness absence but I can assure all parties that this work was completed and is reviewed by our relief replacement pharmacist regularly and efficiently.”

- 4.13 I note the Commissioner states that an email was sent on 17 September 2024 and that it offered three webinars to complete the form. The Commissioner states *“further emails were sent and follow up phone calls made by the Programme Team and LPC with a final extension to the deadline given as Tuesday 22nd October 2024.”* As a result, on 28 November 2024, the Pharmaceutical Services Regulations Committee (PSRC) for Greater Manchester, at its meeting agreed to issue the Breach Notice. The Appellant states that no phone call was received. It is not clear to me how a final extension to 22 October 2024 was communicated if the phone call was not received.
- 4.14 I have not been provided with copies of the emails sent to the pharmacy regarding the required actions and follow-up chases but note that the Appellant does not dispute these emails were sent or received.
- 4.15 The Appellant states that *“We actioned all messages by the initial deadline of 30th September in store.”* However, the Appellant also concedes that *“the MS Form was omitted prior to the workload being completed.”* The Appellant also states it *“manually sent notifications via post prior to this deadline.”* The Appellant has not sent anything to evidence what was completed and submitted to the Commissioner and that the correct action was undertaken.
- 4.16 I am therefore of the view that insufficient evidence has been provided to show that the Appellant did submit the information required for post event messages (PEMs) in line with the Regulations, by the required deadline. However I next must consider whether the failure to provide the information pursuant to Schedule 4 Part 4 Paragraph 35 (3) is a breach which is incapable of remedy. As I noted at 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 cannot be rectified.
- 4.17 The Appellant was required to provide PEMs information as part of patient safety for contractors using EMIS PharmOutcomes IT system. Provision of the requested information would have remedied or rectified the breach. I note the Commissioner did give the Appellant a time limit to provide the information however, the deadline is not mandatory in this provision of the Regulations. Further I am mindful that the Commissioner has not indicated that its records system will not allow for late submissions. As such I consider that the breach by the Appellant is capable of remedy. I consider that the Commissioner should have issued to the Appellant a remedial notice instead of a breach notice.
- 4.18 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”.*
- 4.19 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 provide information on request, it is entirely appropriate to require the Appellant to remedy the breach.

- 4.20 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.
- 4.21 As a result of the comments I make above, I am of the view that:
- 4.21.1 The Appellant did not submit the Post Event Messaging (PEM) MS form within the time limit set by the Commissioner and
- 4.21.2 Such action constitutes a breach of the Appellants terms of service by virtue of Schedule 4, Part 4, paragraph 35(3), which is capable of remedy.
- 4.22 I therefore substitute 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 PEMs information required by the Commissioner. I note the Appellant says it has this information and it has been posted. I consider the Appellant should be able to access this information again and provide it to the Commissioner. 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 how and in what format this information should be provided.

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 with the same wording except for the changes below:
- 5.1.1 Substitute all references to "breach notice" with reference to "remedial notice pursuant to Regulation 70".
- 5.1.2 Substitute the requirement not to repeat the breach notice with the requirement to remedy the breach within the notice period.
- 5.2 The Commissioner must indicate to the Appellant how and in what format the information should be provided. The timescale to remedy will be 30 days from the date of that communication.

**Head of Appeals
NHS Resolution**