

2 December 2024

REF: SHA/26328

**APPEAL AGAINST NORTHAMPTONSHIRE ICB
DECISION REGARDING A BREACH NOTICE AT WELL
PHARMACY**

8th Floor
10 South Colonnade
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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 confirm the decision of the Commissioner to issue the Breach Notice.

A copy of this decision is being sent to:

Well Pharmacy
Northamptonshire ICB

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1 The Breach Notice

A Breach Notice dated 25 September 2024 was sent to Well Pharmacy ("the Appellant") in respect of Great Oakley Medical Centre, Corby, Northampton, NN17 1TR.

1.1 "This is a Breach Notice issued under Regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

1.2 Nature of the breach

1.3 New Medicines Service (NMS) is an Advanced Service within the Community Pharmacy Contractual Framework (CPCF). Pharmacy contractors providing the NMS service are required by the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 to maintain records of the consultations. Contractors providing the NMS service must collate information on the NMSs provided each quarter and this must be provided to East Midlands Primary Care Team via the NHSBSA Information Portal within 10 working days from the last day of the quarter the data refers to.

1.4 NHSBSA have informed the East Midlands Primary Care Team that Well the Pharmacy have claimed NMS payments for at least one of the months during April 2021 and March 2022 however, no quarterly data has been submitted. East Midlands Primary Care Team have requested your pharmacy to submit **1049** claims made between April 2021 and March 2022. However, the pharmacy has failed to submit the data after numerous attempts and has not provided a reason why.

1.5 The NHSBSA information portal has now closed for 2021/22 data input and the pharmacy is now unable to submit the data and therefore remedy the issue.

1.6 East Midlands Primary Care Team therefore referred this matter of non-compliance to the Pharmaceutical Services Regulations Committee on 16th July 2024. The PSRC found the pharmacy to be in breach of the terms of service for failure to provide New Medicines Services information for 2021/2022 when requested.

1.7 East Midlands Primary Care Team have therefore found Well the Pharmacy, Great Oakley Medical Centre, Corby, Northampton, NN17 1TR to be in breach under Regulation 71, in respect of the breach of Schedule 4, Part 4, paragraph 35(3) of the NHS (Pharmaceutical and Local Pharmaceutical services) Regulations 2013.

1.8 You are required to not repeat the breach and provide the New Medicine Service quarterly data to East Midlands Primary Care Team within 10 working days from the last day of the quarter the data refers to, using the NHSBSA portal.

1.9 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 appeals@resolution.nhs.uk or:

1.9.1 Primary Care Appeals, 4th Floor Arena Point, Merrion Way Leeds LS2 8PA

- 1.10 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 27 September 2024 addressed to NHS Resolution, the Appellant appealed against Northamptonshire ICB's ("the Commissioner") decision. The grounds of appeal are:

- 2.1 “I am emailing to appeal the attached breach notice issued on 25th September against Well Pharmacy – Great Oakley Medical Centre.
- 2.2 The nature of the breach states “Contractors providing the NMS service must collate information on the NMSs provided each quarter and this must be provided to East Midlands Primary Care Team via the NHSBSA Information Portal within 10 working days from the last day of the quarter the data refers to.”
- 2.3 My grounds for appeal are that the mandatory NMS quarterly data submission was suspended in 2020 during covid and has remained suspended since. The following information is taken from the Community Pharmacy England and NHS websites:
- 2.4 *“NHS England is asking pharmacy owners to continue to **voluntarily** submit New Medicine Service (NMS) quarterly summary data to the NHS Business Services Authority (NHSBSA) for Quarter 1 (Q1) 2023/24 (April to June 2023).*
- The mandatory requirement to submit this data has been suspended since 2020, due to the COVID-19 pandemic.”*
- 2.5 [NMS: Voluntary quarterly data continues - Community Pharmacy England \(cpe.org.uk\)](https://cpe.org.uk/nms-voluntary-quarterly-data-continues)
- 2.6 [New Medicine Service \(NMS\) | NHSBSA](https://www.nhs.uk/medicines/new-medicine-service/)
- 2.7 The action specified is “You are required to not repeat the breach and provide the New Medicine Service quarterly data to East Midlands Primary Care Team within 10 working days from the last day of the quarter the data refers to, using the NHSBSA portal.” As the quarterly data submission is not a mandatory requirement I believe this should not apply.
- 2.8 Please note that the data to verify the 1049 NMS claims has now been submitted.”
- 2.9 [The Appellant provided a copy of the pages at the links above.]

3 Summary of Representations

This is a summary of representations received on the appeal.

3.1 THE COMMISSIONER

- 3.1.1 “Thank you for your letter dated 01 October 2024; the East Midlands Primary Care Team on behalf of NHS Northamptonshire ICB would like to make the following representations.
- 3.1.2 The New Medicines Service (NMS) is an Advanced Service within the Community Pharmacy Contractual Framework (CPCF). Pharmacy contractors providing the NMS service are required by the Pharmaceutical Services

(Advanced and Enhanced Services) (England) Directions 2013 to maintain records of the consultations.

- 3.1.3 Contractors providing the NMS service must collate information on consultations provided each quarter and this must be provided to East Midlands Primary Care Team via the NHSBSA Information Portal within 10 working days from the last day of the quarter the data refers to.
- 3.1.4 The NHS Business Services Authority (NHSBSA) on behalf of the East Midlands Primary Care Team were requested to undertake a post payment verification exercise for a sample of pharmacies who had submitted claims for the New Medicines Service between April 2021 and March 2022. Well Pharmacy Oakley were included in this sample as they had submitted a total of 1049 claims during this period.
- 3.1.5 The pharmacy has been contacted on a number of occasions to provide evidence to support the 1049 claims made, however the pharmacy has not responded to any of the contacts made by the NHSBSA and has not provided a reason why. A copy of the timeline is included with the representation.
- 3.1.6 The East Midlands Primary Care Team therefore referred this matter of non-compliance to the Pharmaceutical Services Regulations Committee (PSRC) on 16 July 2024. The PSRC found the pharmacy to be in breach of the terms of service in respect of the breach of Schedule 4, Part 4, paragraph 35(3) for failure to provide evidence for claims made for the period of April 2021 and March 2022.
- 3.1.7 Therefore, a breach notice was issued to the pharmacy on 25 September 2024 however, though the correct regulation was applied on the breach notice, the narrative within the breach notice was incorrect.
- 3.1.8 The narrative stated that claims for consultations had not been submitted, however this should have read that the pharmacy had failed to provide evidence of the claims they had made. To date the pharmacy have still not provided evidence of the 1049 claims made and therefore they are still in breach of Schedule 4, Part 4, paragraph 35(3)."
- 3.1.9 [The Commissioner provided a copy of the timeline referred to above.]

4 Observations

4.1 THE APPELLANT

- 4.1.1 "[The Commissioner's] letter dated 23rd October states "to date the pharmacy have still not provided evidence of the 1049 claims made and therefore they are still in breach of Schedule 4, Part 4, paragraph 35(3)". I have attached copies of the correspondence with NHSBSA which confirms the receipt of the post payment verification evidence on 4th October. The result of the verification exercise being completed is also attached. I therefore don't believe that the pharmacy are still in breach of the regulation as stated in the letter.
- 4.1.2 Whilst I acknowledge the pharmacy did not engage with the post payment verification process as requested, the requirement of the breach doesn't relate to this element, it relates to the non-submission of the New Medicine Services quarterly data to East Midlands Primary Care Team. During the period stated on the breach notice (April 2021 to March 2022), the submission of New Medicine Quarterly data was a voluntary activity, not a mandatory one and as such non-submission should not be considered as a breach.
- 4.1.3 The [NHSBSA website](#) states:

4.1.4 **NMS quarterly data submissions**

Pharmacy contractors will know that the requirement to submit their completed NMS quarterly summary data to us had been suspended since 2020 due to the COVID-19 pandemic.

Earlier this year, NHS England agreed with CPE to restart submissions of NMS quarterly summary data on a voluntary basis to support long term monitoring. This is part of ongoing work to expand the NMS to include more therapeutic areas, and to provide evidence of service delivery for the new therapeutic areas.

Manual submissions of summary data were discontinued once the API was implemented. Quarter 2 of 2023 to 24 (1 July to 30 September 2023) was the final data return requested to be submitted to us

4.1.5 I would be grateful if you could take into account these additional observations.”

4.1.6 [The Appellant provided copy emails dated 3 and 22 October 2024 both from the NHS BSA to the Appellant.]

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 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 “pharmacy has failed to submit the data after numerous attempts and has not provided a reason why.” Further in its representations, the Commissioner provided a timeline detailing its communications with the Appellant together with copy emails, which have not been disputed by the Appellant.

- 5.7 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 provide information in relation to NMS claims made between April 2021 and March 2022.
- 5.9 The Commissioner found the Appellant to be in breach under Regulation 71, in respect of the breach of Schedule 4, Part 4, paragraph 35(3) of the Regulations 2013.
- 5.10 I note that paragraph 35(3), Part 4, Schedule 4 of the Regulations states:
- 35. Inspections and access to information*
- (3) P must, at the request of the NHS England 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 NHS England, in connection with its functions that relate to pharmaceutical services*
- 5.11 The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (the "Directions") are included in Part VIC of the Drug Tariff and are made under section 127 of the NHS Act 2006. The Regulations define "directed services" as additional pharmaceutical services provided in accordance with directions under section 127 of the NHS Act 2006. I therefore consider that obligations contained in the Directions are deemed to be terms of service by virtue of Regulation 11 and the ability to issue a breach notice under Regulation 71 applies to a failure to comply with such obligations.
- 5.12 I note that Regulation 11(1) makes clear that terms of service include any provisions affecting an NHS pharmacist's rights or obligations that are:
- 5.12.1 included in the Drug Tariff; and
- 5.12.2 included in any arrangements that NHS England makes with an NHS pharmacist for the provision of any directed services.
- 5.13 I note paragraph 7(l) of the Directions states:
- P ensures that a written record (which may be an electronic record) of each consultation carried out by or on behalf of P as part of P's New Medicine Service is prepared by the registered pharmacist who carried out the consultation and includes the approved data ("approved" for these purposes means approved by the NHSCB);*
- 5.14 Paragraph 7(m) states:
- P provides information from those records to the NHSCB or the Secretary of State, on request, in the manner approved for this purpose, and for the purposes approved, by the NHSCB;*
- 5.15 The Commissioner states that "Contractors providing the NMS service must collate information on the NMSs provided each quarter and this must be provided to East Midlands Primary Care Team via the NHSBSA Information Portal within 10 working days from the last day of the quarter the data refers to."

- 5.16 I note in its representations, the Commissioner seeks to amend an error in the Breach Notice. The Commissioner states that *“The narrative stated that claims for consultations had not been submitted, however this should have read that the pharmacy had failed to provide evidence of the claims they had made. To date the pharmacy have still not provided evidence of the 1049 claims made and therefore they are still in breach of Schedule 4, Part 4, paragraph 35(3).”* Therefore, there is no dispute that claims were made.
- 5.17 The Appellant contends that the mandatory requirement to submit data in relation to NMS was suspended in 2020 during Covid and remains suspended since. The Appellant provides an extract from the NHS BSA’s website, which states:
- 5.17.1 **NMS quarterly data submissions**
- Pharmacy contractors will know that the requirement to submit their completed NMS quarterly summary data to us had been suspended since 2020 due to the COVID-19 pandemic.*
- Earlier this year, NHS England agreed with CPE to restart submissions of NMS quarterly summary data on a voluntary basis to support long term monitoring. This is part of ongoing work to expand the NMS to include more therapeutic areas, and to provide evidence of service delivery for the new therapeutic areas.*
- Manual submissions of summary data were discontinued once the API was implemented. Quarter 2 of 2023 to 24 (1 July to 30 September 2023) was the final data return requested to be submitted to us.*
- 5.18 The passage referred to by the Appellant is in relation to the voluntary submission of quarterly summary data and as such, I am of the view that the Appellant cannot be found in breach on this basis. However, I do not consider this view applies in relation to providing evidence to support the claims for payment.
- 5.19 The request to submit evidence to support the claims was made after the period in question (April 2021 to March 2022) and, in line with its terms of service, paragraph 35(3) of Schedule 4, requires the Appellant to provide information on request. Therefore even if the data had not been submitted at the time, there was a specific request to provide that information.
- 5.20 In this regard, I note that this information has been requested following a post-payment verification (“PPV”) exercise undertaken by the NHS BSA on behalf of the Commissioner. The Appellant was selected as part of the exercise as it was one of the highest claiming pharmacies for 2021/2022.
- 5.21 In an email dated 24 May 2023, advising the Appellant of the PPV exercise, the NHS BSA states *“Pharmacists providing the service must also retain these records, to support ongoing provision of the service to patients, their future care and audit of the service.”* I note the Appellant does not dispute receipt of this email, which explains the requirement for contractors to retain records for audit of the service, that being the PPV exercise.
- 5.22 The Commissioner in its representations states that *“the NHSBSA information portal has now closed for 2021/22 data input and the pharmacy is now unable to submit the data and therefore remedy the issue.”*
- 5.23 I note the Appellant’s contention that it has since submitted the data which was considered by the NHS BSA. The Appellant provided a copy email dated 3 October 2024 from the NHS BSA acknowledging receipt of information provided by the Appellant and a further email dated 22 October 2024 from the NHS BSA detailing the

outcome of the PPV exercise. The Appellant is therefore of the view that it is no longer in breach of the Regulation.

- 5.24 In the email dated 22 October 2024, the NHS BSA states that *“Our records show that your pharmacy claimed a total of 1049 NMS during this time, however the evidence provided by the pharmacy means the Provider Assurance Team were unable to verify 102 of the claims made.*

Although 1128 NMS claims were received, 149 of the NMS evidence were not for the requested time period requested. There were also 44 duplicated patients within the NMS evidence and a shortfall of 58 NMS evidence in December 2021.” I note that there is a still a shortfall in the information provided.

- 5.25 Further, when considering the Appellant’s comment that it believes it is no longer in breach, I note Regulation 70 of the Regulations, which states:

5.25.1 *“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.”*

- 5.26 The Appellant’s interpretation that as he has now provided the information, he is not in breach, is not correct as there was a failure to supply the appropriate information at the time it was requested and which met the requirements of the PPV exercise. 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. I note the information provided was not sufficient evidence in accordance with the requirements of the PPV exercise and as the portal has now closed, the Appellant is unable to remedy the breach.

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

5.27.1 the Appellant failed to provide evidence of the 1049 claims as part of the PPV exercise undertaken by the NHS BSA;

5.27.2 such action constitutes a breach of the Appellant’s terms of service as set out in paragraph 35(3) of Schedule 4 to the Regulations;

5.27.3 the Commissioner was entitled to issue the Breach Notice.

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 confirm the decision of the Commissioner to issue the Breach Notice.

**Head of Appeals
NHS Resolution**