

9 April 2025

REF: SHA/26444

**APPEAL AGAINST NHS LINCOLNSHIRE ICB DECISION
REGARDING A BREACH NOTICE AT SKEGNESS
PHARMACY (FH452)**

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

Tel: 020 3928 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:

Skegness Pharmacy
East Midlands Primary Care Team (on behalf of NHS Lincolnshire ICB)

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1 The Breach Notice

A Breach Notice dated 20 December 2024 was sent to Skegness Pharmacy ("the Appellant") in respect of 13 – 15 Lumley Road, Skegness, Lincolnshire, PE25 3LL.

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

Nature of the breach

- 1.2 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 Lincolnshire Integrated Care Board) or person authorised in writing by of [sic] the East Midlands Primary Care Team (on behalf of Lincolnshire Integrated Care Board) to make request, send to the East Midlands Primary Care Team or that person by means of an electronic communication, a duly completed questionnaire.
- 1.3 In order to demonstrate compliance with the community pharmacy assurance framework, of The East Midlands Primary Care Team (on behalf of Lincolnshire Integrated Care Board) and NHS BSA on behalf of The East Midlands Primary Care Team (on behalf of Lincolnshire Integrated Care Board) requested completion of the full questionnaire on a number of occasions (08 October 2024, 15 October 2024, 21 October 2024 and 28 October 2024). However, the pharmacy failed to submit the full questionnaire by the deadline and has provided no valid reason why. The questionnaire closed on 31 October 2024 therefore the breach of the terms of service is incapable of remedy.
- 1.4 The East Midlands Primary Care Team (on behalf of Lincolnshire Integrated Care Board) therefore referred this matter of non-compliance to the Pharmaceutical Services Regulations Committee on 18 December 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.
- 1.5 The East Midlands Primary Care Team (on behalf of Lincolnshire Integrated Care Board) have therefore found Skegness Pharmacy, 13-15 Lumley Road, Skegness, Lincolnshire, PE25 3LL 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.
- 1.6 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 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 6 January 2025 addressed to NHS Resolution, the Appellant appealed against Lincolnshire ICB ("the Commissioner") decision. The grounds of appeal are:

- 2.1 "I hope this message finds you well. I am writing to formally appeal the breach notice related to the Community Pharmacy Assurance Framework (CPAF) concerning the failure to complete the full questionnaire within the required timeframe. I acknowledge that the questionnaire was not submitted as expected and wish to explain the circumstances that led to this delay.
- 2.2 I acquired Skegness Pharmacy on 27 July 2024, and since then, I have been working diligently to address various aspects of the business, including SOPs, staffing, suppliers, administration, and compliance with clinical governance standards. Unfortunately, this transition period led to a delay in opening and monitoring the NHS email account, which meant that I was not aware of the timeframe to complete the CPAF questionnaire until it was too late.
- 2.3 In addition, the submission window for the questionnaire fell during the month of October, which was particularly challenging due to the commencement of the winter Flu and COVID vaccination services. The pharmacy was under significant pressure as we worked very hard to deliver 1911 COVID-19 vaccines and 1183 Flu vaccines in the month of October to our community, and this further contributed to my inability to respond to the CPAF questionnaire in a timely manner.
- 2.4 I want to assure you that I have thoroughly reviewed the CPAF questionnaire and can confidently confirm that our pharmacy is fully meeting all the prerequisites and standards outlined in the framework. I am committed to maintaining the highest level of care and compliance with all NHS requirements, and I take this responsibility very seriously.
- 2.5 Given the circumstances surrounding the acquisition of the pharmacy and the increased demands placed on the business during the vaccination season, I respectfully request your understanding and reconsideration of the breach. I would be very grateful for the opportunity to submit the completed questionnaire and demonstrate our commitment to upholding the necessary standards.
- 2.6 Thank you for your time and consideration. If any further information or clarification is required, please do not hesitate to contact me. I look forward to your response."

3 Summary of Representations

This is a summary of representations received on the appeal.

3.1 THE COMMISSIONER

- 3.1.1 “Thank you for the representations received by the East Midlands Primary Care Team on behalf of Lincolnshire Integrated Care Boards. We are sorry to hear that Skegness Pharmacy (FH452) have appealed against the breach notice issued and have provided representations below to support the decision to issue the breach notices.
- 3.1.2 Schedule 4, Part 4, Paragraph 35(5) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended states that:
- 3.1.3 *‘A Pharmacy must at the request of The National Health Service Commissioning Board (NHSCB) or a person authorised 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 NHSCB; and*
- (b) for the purpose of enabling NHSCB, or a person authorised in writing by NHSCB, to determine whether or when it is necessary or expedient for a person authorised in writing by NHSCB to undertake an inspection of P’s premises pursuant to sub-paragraph (1).’*
- 3.1.4 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).
- 3.1.5 East Midlands Primary Care Team on behalf of Lincolnshire Integrated Care Board (ICB) use the CPAF to monitor community pharmacy contractors’ compliance with the terms of the Community Pharmacy Contractual Framework (CPCF).
- 3.1.6 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.
- 3.1.7 Skegness Pharmacy (FH452) successfully completed the short screening questionnaire before the allocated deadline of 31 July 2024 and were selected to complete the full, long form questionnaire as per the full questionnaire criteria as they were a new inclusion on the Lincolnshire Health and Wellbeing Board Pharmaceutical List between June 2023 and July 2024.
- 3.1.8 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 full screening questionnaire ran from the 1 October 2024 – 31 October 2024 and is a more in depth questionnaire asking for details of completed Standard Operating Procedures, Essential Services and Clinical Governance the Pharmacy are required to conduct and complete.

- 3.1.9 East Midlands Primary Care Team and the NHS Business Service Authority on behalf of the commissioner, contacted the pharmacies selected to complete the long questionnaire on a number of occasions. The dates of contact to Pharmacies from East Midlands Primary Care Team are listed below;
- 3.1.9.1 8 October 2024
- 3.1.9.2 15 October 2024
- 3.1.9.3 21 October 2024
- 3.1.9.4 28 October 2024
- 3.1.10 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 would result in the issue of a breach notice.
- 3.1.11 Additional reminders are also posted on other mediums such as the Community Pharmacy England website [2024/25 Community Pharmacy Assurance Framework \(CPAF\) screening questionnaire has opened - Community Pharmacy England/Full CPAF Questionnaire 2024/25 - Community Pharmacy England](#) and the NHSBSA 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.
- 3.1.12 As a result of Skegness Pharmacy (FH452) failing to submit responses to the full CPAF questionnaire the decision to issue a Breach Notice for failure to complete the requested full CPAF questionnaire was granted at the Pharmaceutical Services Regulation Committee (PSRC) on 18 December 2024 and the Breach Notice under Regulation 71 in respect of Schedule 4, Part 4, Paragraph 35(5) of the NHS (Pharmaceuticals and Local Pharmaceutical Services) Regulations 2013 was issued to the Pharmacy on 20 December 2024.
- 3.1.13 In response to the Appellant's letter of representation, the East Midlands Primary Care Team (EMPCT) do empathise with the Provider and the challenges they faced whilst the Change of Ownership process was in progress, including the number of flu and Covid-19 vaccinations administered and the time frame for completion of the full questionnaire. The EMPCT would like to take this opportunity to thank them for the work that they undertook during this very busy period of time. However, the CPAF questionnaire has now been compulsory since 2021 and forms part of the pharmaceutical regulations and the terms of service that every Pharmacy providing NHS services must adhere to. As per the criteria for completion of the long questionnaire, the pharmacy was selected and the East Midlands Primary Care Team received no communication of concerns regarding the selection criteria or ability to complete the questionnaire from the Appellant.
- 3.1.14 I would like to take this opportunity to respond to any further representations provided by Skegness Pharmacy (FH452), 13-15 Lumley Road, Skegness, Lincolnshire, PE25 3LL."

4 Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

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 East Midlands Primary Care Team (on behalf of Lincolnshire Integrated Care Board) and NHS BSA on behalf of the East Midlands Integrated Care Board) requested completion of the full questionnaire on a number of occasions ... 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 communications sent ‘on a number of occasions’, the Appellant has not disputed that these emails were sent or received.
- 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 Community Pharmacy Assurance Framework (CPAF) questionnaire.
- 5.9 I note that “Inspections and access to information” is found in Schedule 4, Part 4, ‘Other Terms of Services’ under Paragraph 35 and states:

35. Inspections and access to information

(1) An NHS pharmacist (P) must allow persons authorised in writing by NHS England 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 arrangements 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 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 NHS England, in connection with its functions that relate to pharmaceutical services.

(4) P must, at the request of NHS England, send to NHS England by means of an electronic communication of the type specified in the request any information to which a person authorised in writing by NHS England 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 NHS England to request that P convert that information into a form which means that it may be sent by that form of electronic communication (and NHS England does so request)

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

(a) in a format approved by NHS England; and

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

(6) Before information is requested pursuant to sub-paragraph (5), NHS England 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 comments that the CPAF is used to monitor compliance with the terms of the Community Pharmacy Contractual Framework (CPCF). The first stage of the CPAF process consists of a questionnaire of 10 questions which pharmacy contractors are asked to consider and self-assess against certain aspects of the terms of service. I note that the Appellant successfully completed the first questionnaire before the deadline of 31 July 2024.
- 5.11 The Commissioner states that the full questionnaire, which the Appellant was invited to complete due to their recent admission to the Lincolnshire HWB pharmaceutical list, ran from 1 to 31 October 2024. The Commissioner further states that it contacted the Appellant on four occasions during October 2024. The Commissioner comments that additional reminders detailing the deadlines and how to complete the questionnaire were also posted on other mediums such as the Community Pharmacy England website and the NHSBSA website. Links have been provided in the Commissioner's representations and have not been disputed by the Appellant. I note that no response was received from the Appellant to the CPAF reminder emails and therefore the Breach Notice was subsequently issued.
- 5.12 I note the Appellant stated in its appeal that it acquired the pharmacy in July 2024 and that there was "a delay in opening and monitoring the NHS email account, which meant that I was not aware of the timeframe to complete the CPAF questionnaire until it was too late."
- 5.13 I note that under Schedule 4, Part 4, Paragraph 29C 'Contact via NHSmail, pharmacy profiles and the Central Alerting System' it states:
- 29C. –**
- (1) An NHS pharmacist (P) must ensure that pharmacy staff at pharmacy premises (including locums) have access to, and are able to send and receive NHSmail from, a premises specific NHSmail account.
- (2) P must ensure that at least two members of the pharmacy staff have live, linked NHSmail accounts to the premises specific NHSmail account (unless fewer than two members of the pharmacy staff are engaged in the provision of NHS services).
- 5.14 Given the above requirements, it is clear that the Appellant has a responsibility to ensure that its NHSmail box is accessible and monitored by more than one member of staff. This does not appear to have happened and therefore communications on several occasions relating to the questionnaire were not responded to.
- 5.15 I have had regard to the Appellant's comments regarding the work pressures at the time which led to the oversight in not submitting the questionnaire and that the

Appellant has indicated that it has “*thoroughly reviewed the CPAF questionnaire and can confidently confirm that our pharmacy is fully meeting all the prerequisites and standards outlined in the framework*”. Whilst recognising the Appellant’s valuable contribution to providing vaccination services, I am of the view that the responsibility lies with the Appellant to make sure that it checks its emails regularly, regardless of workload, and has an understanding of the CPAF requirements.

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

5.16.1 the Appellant did not complete the CPAF Questionnaire by the required deadline;

5.16.2 such action constitutes a breach of the Appellant’s terms of service as set out in paragraph 35(5) of Schedule 4 to the Regulations; and

5.16.3 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**