

11 April 2024

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

REF: SHA/26151

**APPEAL AGAINST FRIMLEY ICB DECISION
REGARDING A BREACH NOTICE AT SALTS
HEALTHCARE LTD T/A HEALTHLINK (FQT79) -
HEALTHLINK HOUSE/THE ANNEX, SOUTHWICK
STREET, SOUTHWICK, WEST SUSSEX BN24 4TE**

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 substitute the decision of the Commissioner to issue a breach notice with a decision to not issue a breach notice.

A copy of this decision is being sent to:

Salts Healthcare Ltd
Frimley ICB

Advise / Resolve / Learn

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1 The Breach Notice

A Breach Notice dated 12 January 2024 was sent to Salts Healthcare Ltd t/a Healthlink ("the Appellant") in respect of Healthlink House/The Annex, Southwick Street, Southwick, West Sussex, BN24 4TE. The Breach Notice stated:

- 1.1 **"Name of contractor:** Salts Healthcare Ltd t/a Healthlink
- 1.2 **Address of premises:** Healthlink House/The Annex, Southwick Street, Southwick, West Sussex, BN24 4TE
- 1.3 **Date of inclusion in the pharmaceutical list for the area of West Sussex Health and Wellbeing Board:**
- 1.4 **This is a breach notice issued under regulation 71 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.**
- 1.5 **Nature of the breach:**
- 1.6 Healthlink, Healthlink House/The Annex, Southwick Street, Southwick, West Sussex, BN24 4TE has not completed the clinical governance annual self-assessment of compliance for 2022/2023 in breach of Schedule 4 Paragraph 28(2)(f)(ii) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.
- 1.7 The pharmacy has not completed the Data Security and Protection Toolkit for 2022/23 by the deadline of 30th June 2023.
- 1.8 **You are required to not repeat the breach.**
- 1.9 You have the right to appeal to the Secretary of State against 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 receiving this notice to: nhsr.appeals@nhs.net or write to:
- 1.10 NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU
- 1.11 Please note that should you fail to comply with the requirements of this breach notice, we may take further action in relation to the 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 29 January 2024 addressed to NHS Resolution, the Appellant appealed against Frimley ICB's ("the Commissioner") decision. The grounds of appeal are:

- 2.1 "We are in receipt of the attached Breach Notice for not completing the DSP Toolkit for 2022/23.
- 2.2 However, we wish to appeal as we did complete the DSP Toolkit as an organisation (8JN47) which includes this dispensary and received notification of the standard being met on 26th June 2023 for the year in question. Please see details below. [Appendix A provided].
- 2.3 May we also advise that we are not a Community Pharmacy but are a Dispensing Appliance Contractor.
- 2.4 If you could please acknowledge receipt of this Appeal and our compliance to Frimley ICB, it would be appreciated.
- 2.5 Any queries, please do not hesitate to contact me."

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 30 January 2024 regarding the appeal made by Salts Healthcare Ltd against the decision to issue a breach notice for non-completion of the Data Security and Protection (DSP) Toolkit for 2022/23.
- 3.1.2 The appeal is made on the grounds that the Pharmacy has completed the DSP toolkit for 2022/23 and has provided a certificate from NHS Digital as proof of completion.
- 3.1.3 Community Pharmacy contractors (including Dispensing Appliance Contractors) are required to give assurances to the NHS annually on their data security and protection systems and procedures via the online assessment, the toolkit. The deadline for community pharmacies to complete the 2022/23 data and security protection toolkit was 30 June 2023.
- 3.1.4 On 27 September 2023 an email was sent to the Pharmacy to advise them that records indicated they had not completed the toolkit (copy at Annex 1) [see Appendix B]. They were then required to provide evidence that they had either completed the toolkit or to provide reasons for why they had not done so. No response was received from the Pharmacy.
- 3.1.5 On 11 October 2023 a second email was sent to the Pharmacy giving them a further opportunity to provide a response (copy at Annex 2), [see Appendix B] again no response was received from the Pharmacy.
- 3.1.6 When the Pharmaceutical Services Regulations Committee (PSRC) for Sussex Integrated Care Board on 30 November 2023 considered whether a breach notice should be issued or not, no evidence had been provided by the Pharmacy to demonstrate completion of the DSP toolkit.
- 3.1.7 Following receipt of the appeal documentation, including a copy of the DSP toolkit certificate, we note that the pharmacy ODS code is different to the code that is used on the certificate, so when using the ODS code as reflected in the pharmaceutical list (FQT79), the pharmacy still appears to have not completed the toolkit, see extract from the DSP Toolkit website.

ODS	Organisation name	Statue	Published
FQT79	SALTS MEDILINK (FQT79)	18/19 Standards Met	26/03/2019

3.1.8 However, if we use the code on the certificate (8JN47), which we do not recognise, then Salts Healthcare Ltd appears to have published the toolkit for their organisation but there are no other sites/pharmacies within their organisation listed.”

4 Observations

4.1 THE APPELLANT

4.1.1 “I am writing to acknowledge receipt of the attached notification with regards [sic] to our appeal to the breach notice issued regarding our Data Security and Protection Toolkit submission for 2022/2023. As you can see from the attached correspondence, [see Appendix C] we acted upon advice from NHS Digital back in March 2017 which led us to believe that our batch code would detail compliance for our other ODS codes. We apologise for missing the email communication querying our submission which could have resulted in no breach notification. As a corrective measure, we have added further to our standard operating procedures to ensure we do not miss future email correspondence.

4.1.2 I trust that this draws the matter to a conclusion, however please do not hesitate to contact me should you have any further queries or concerns.”

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 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 Appellant seeks to appeal against the decision of the Commissioner to issue the Breach Notice dated 12 January 2024 for its failure to complete the Data Security and Protection Toolkit for 2022/2023.

- 5.6 The Commissioner, in its representations, states “on 27 September 2023 an email was sent to the Pharmacy to advise them that records indicated they had not completed the toolkit”. The Commissioner noted “no response was received from the Pharmacy”. The Commissioner sent a second email on 11 October 2023 providing the Appellant with a further opportunity to respond. However no response was received. I note the email address on 27 September 2023 was pharmacy.fqt79@nhs.net and the email address on 11 October was dac.fqt79@nhs.net. It is not clear if either or both these email addresses are valid but I note the Appellant has not disputed that these emails were received.
- 5.7 The Appellant had an opportunity at this point to enter into local dispute resolution with the Commissioner but did not do so.
- 5.8 The Commissioner found the Appellant in breach of paragraph 28(2)(f)(ii), Schedule 4 of the Regulations, which states:
- “28.—(1) An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance [F2 and for the promotion of healthy living].*
- (2) For these purposes a system of clinical governance [F3 and for the promotion of healthy living] is “acceptable” if it is considered acceptable by the NHSCB and comprises the following components—*
- f) an information governance programme, which provides for—*
- ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment;*
- and for the purposes of this sub-paragraph, “approved” means approved by the NHSCB.”*
- 5.9 The Breach Notice stated that the pharmacy had not completed the Data Security and Protection Toolkit for 2022/2023 by the deadline of 30 June 2023.
- 5.10 I note the Appellant states it is compliant and the standard was met on 26 June 2023. The Appellant has provided a copy email dated 26 June 2023 from the DSPT Toolkit Team acknowledging publication:
- “Thank you for publishing your 2022-23 (version 5) Standards Met Data Security and Protection Toolkit assessment for SALTS HEALTHCARE LTD (8JN47) on 26/06/2023 11:00.*
- Everyone who uses health and care services should be able to trust that their personal confidential data is protected. Publishing your Data Security and Protection Toolkit provides assurance that your organisation is practising good data security and that personal information is handled correctly.*
- Your DSP Toolkit status of Standards Met is publicly available for your service users, commissioners, partner organisations and the public at <https://www.dsptoolkit.nhs.uk/OrganisationSearch/8JN47>*
- A certificate that confirms your compliance is available by opening your latest publication (from the “View previous publications” link).”*
- 5.11 The Appellant has provided a table for Organisation code 8JN47 with the publication history showing status “Standards Met” and the date published from 2018/19 version 1 each year up to 2022/23 version 5.

5.12 I note the Commissioner, in its representations, states:

“Following receipt of the appeal documentation, including a copy of the DSP toolkit certificate, we note that the pharmacy ODS code is different to the code that is used on the certificate, so when using the ODS code as reflected in the pharmaceutical list (FQT79), the pharmacy still appears to have not completed the toolkit.

However, if we use the code on the certificate (8JN47), which we do not recognise, then Salts Healthcare Ltd appears to have published the toolkit for their organisation but there are no other sites/pharmacies within their organisation listed.”

5.13 In its observations, the Appellant states

“we acted upon advice from NHS Digital back in March 2017 which led us to believe that our batch code would detail compliance for our other ODS codes. We apologise for missing the email communication querying our submission which could have resulted in no breach notification. As a corrective measure, we have added further to our standard operating procedures to ensure we do not miss future email correspondence.”

5.14 The Appellant has provided a copy of the email trail between the Appellant and NHS Digital between 23 and 27 March 2017 in which NHS Digital advised how to add individual site information, the Appellant added the additional dispensing site information, asking NHS Digital to check it, with NHS Digital replying “All looks great to me”.

5.15 I have considered the information before me and conclude that the parties could have resolved this matter locally had the Appellant responded to the emails sent, though I am mindful that the Commissioner used two different email addresses. However neither party has disputed that local dispute resolution has not been exhausted. Given that both parties do not dispute that local dispute resolution has been exhausted I am satisfied that I can deal with this matter.

5.16 I next consider whether there was a breach in ‘submission’ of the Data Security and Protection Toolkit, not a breach in ‘completion’ as stated in the Breach Notice.

5.17 On reviewing the information above, I note the Appellant has submitted, in good faith, a Data Security and Protection toolkit for organisation code 8JN47, which it believed covered the site FQT79 within the timescale requested. While the Commissioner does not recognise the code 8JN47 for the organisation to cover the individual site FQT79, the Commissioner was able to access that assessment in line with paragraph 28(2)(f)(ii) as quoted above.

5.18 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.

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

5.19.1 the Appellant did submit the Data Security and Protection Toolkit for 2022/23 by the deadline set by the Commissioner; and

5.19.2 such action does not constitute a breach of the Appellant’s terms of service by virtue of paragraph 28(2)(f)(ii).

5.20 Therefore on the basis of this information I consider it appropriate to substitute a decision to issue the breach notice with a decision to not issue a breach notice.

5.21 As an aside, I suggest that the parties should agree on one nhs.net email address to correspond with each other to avoid any future miscommunication. I note the Appellant has stated it has added further to its standard operating procedures to ensure it does not miss future email correspondence.

5.22 I further note that when it issued the Breach Notice on 12 January 2024, the Commissioner, in its email, stated:

“Despite reminders that were sent to all pharmacies on 21 June 2023 and 27 June 2023 your pharmacy failed to complete the DSP toolkit for 2022/23, therefore, a breach notice has been issued and is attached.

*As we are currently not assured on your data security and protection systems you are required to complete the 2023/24 toolkit by **9 February 2024**.*

Please confirm by return email when the 2023/24 toolkit has been completed.”

5.23 I have not been provided with any further information on the 2023/24 toolkit submission so have no further comment to make in this regard.

6 Decision

6.1 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations I substitute the decision of the Commissioner to issue a breach notice with a decision to not issue a breach notice.

**Head of Appeals
NHS Resolution**