

Breach Process for non-compliance with National Health Service (Ophthalmic Services) (Wales) Regulations 2023

1. Purpose

This document outlines the All Wales Health Boards process for managing any breach of the NHS (Ophthalmic Services) (Wales) Regulations 2023 and Clinical Service Guidance (Clinical Manuals).

2. Scope

This process applies to all Optometric Contractors providing any level of NHS ophthalmic services under the Regulations and replaces all previous breach processes issued.

3. Definition and Examples of Non-Compliance

A breach is when a Contractor fails to meet the requirements set out in the NHS (Ophthalmic Services) (Wales) Regulations 2023 and supporting Clinical Service Guidance. This may include, but is not limited to:

- service delivery requirements
- approval for changes to core hours
- record keeping
- inappropriate claiming
- clinical governance
- compliance with mandatory reporting
- attendance at Optometry Collaborative Meetings including no approval for buddy arrangements.

4. Monitoring and Detection

The Health Board monitors compliance through audit, claims review, attendance logs and regulatory oversight.

5. Escalation Process

In accordance with the signed declaration, each Contractor is obligated to comply with the Terms of Service as included within the Welsh Government Regulations and Clinical Service Guidance (Clinical Manuals). Failure to do so will trigger the following escalation process:

In exceptional circumstances the Health Board may escalate directly to Level 3 for serious non-compliance and breaches. This flexibility is at Health Board discretion to use as appropriate.

Level 1: First Identified Non-Compliance

- a) The Health Board Primary Care Team will write to the Contractor and remind them of their obligations under The NHS (Ophthalmic Services) (Wales) Regulations 2023.
- b) The Contractor will also be provided with information regarding the Breach Process.
- c) The Contractor will be offered support and provided with clarity regarding the regulatory requirement.
- d) The Health Board may wish to signpost the Contractor to their local Regional Optical Committee for further support and guidance.
- e) Contractors will have the right to dispute any identified non-compliance, which will need to be evidence based.

Next Steps for Level 1:

- If the Contractor addresses the area of non-compliance the escalation process will conclude.
- If non-compliance persists, the escalation process will advance to Level 2.

Level 2: Continued Non-compliance

- a) The Primary Care Team will issue a formal Remedial Breach Notice (Appendix 1)
- b) The Contractor will be required to provide written assurance within 28 days, detailing an action plan to address non-compliance.
- c) Should the Contractor fail to provide the required assurance within 28 days, the Primary Care Team will arrange a face-to-face meeting either at the Contractor's practice or via TEAMS to discuss the non-compliance and review engagement with the Health Board.
- d) Repeated breaches may result in further formal action and progression within the escalation process.

Next Steps for Level 2:

- If the Contractor addresses the area of non-compliance without further issues, the escalation process will conclude.
- If non-compliance continues, the process will escalate to Level 3.

Level 3: Persistent, Repeated or Serious Non-Compliance

- a) The Primary Care Team will issue a formal Breach Notice to the Contractor (Appendix 2 and 3)
- b) The Contractor will be required to provide written assurance within 28 days, confirming their commitment to comply with the regulations and a detailed action plan regarding how this will be addressed.
- c) Failure to provide the requested assurance within the 28-day period will result in the Health Board exercising its right to terminate the provision of NHS services by the Contractor due to non-compliance (Appendix 4).

Next Steps for Level 3:

- If the Contractor addresses the area of non-compliance without further issues, the escalation process will conclude (Appendix 5).

6. Exceptional Circumstances

The Health Board will consider exceptional circumstances for non-compliance. This consideration will be given solely to Contractors who actively engage with and provide a valid explanation to the Health

Board regarding the non-compliance; except where this is not possible. For further information on exceptional circumstances, please see 'Supporting Information'.

7. Termination

The Health Board will not exercise its right to terminate the contract for the provision of NHS services unless it is convinced that the cumulative effect of the breach is sufficiently significant that permitting the Contractor to continue would undermine the efficiency of the services as stipulated under the regulations. This includes cases in which the Contractor's non-compliance is intermittent, resulting in multiple resetting of the Breach escalation process (e.g. initial non-compliance, non-compliance addressed and then non-compliance repeated).

Failure to provide written assurance will be reviewed by the [HB Primary Care Panel], which will determine the appropriate course of action, including potential contract termination. The Health Board will also liaise with the representative body for NHS Contractors' statutory NHS Optical professional group, the [Regional Optical Committee]

8. NHS Dispute Resolution Procedure

Local Resolution of Disputes

- a) The Contractor and the Health Board must make reasonable efforts to resolve any dispute arising from the NHS (Ophthalmic Services) (Wales) Regulations 2023, associated Clinical Service Guidance, or this Breach Process.
- b) Both parties should communicate openly and cooperate with the aim of achieving a timely and mutually acceptable resolution before escalating the matter.
- c) The Contractor may request support from their representative body, including the relevant Regional Optical Committee. The Health Board may also engage with such bodies where appropriate.
- d) Where local resolution is not reasonably practicable within required timescales, the Health Board may proceed directly to formal processes.

Escalation to Formal Dispute Resolution

- a) Where a dispute cannot be resolved locally, either party may refer the matter for formal determination via the Local Assessment Appeal Panel (Optometry).
- b) Referrals must be made in writing to the appropriate Executive Director for the Health Board within 4 weeks and should include:
 - the names and addresses of the parties involved;
 - sufficient details describing the nature of the dispute; and
 - copies of any relevant correspondence or documentation relating to the matter.

- c) The Local Assessment Appeal Panel dealing with a dispute should acknowledge receipt, in writing, of the practice dispute within 7 days. The practice and the Health Board will have 28 days in which to present any further evidence / ask for further evidence why it disputes the outcome of the Breach Process. The Panel will aim to conclude proceedings within 6 weeks of receipt of all representations.
- d) A representative of the practice may elect to attend the Local Assessment Appeal Panel (Optometry).
- e) The Panel's decision will be final within the Health Board's local dispute resolution process.

Membership of the Local Assessment Appeal Panel (Optometry)

Members of the Local Assessment Appeal Panel dealing with an optometry breach or dispute shall be:

- A Health Board Director of Primary Care, Associate Medical Director, or senior member of the primary care/optometry team, who is not party to the contract or directly involved in the case.
- An Optometric Committee representative (e.g. from the relevant Regional Optometric Committee (ROC) or equivalent professional body), who does not represent practitioners in the area of the Health Board which is a party to the contract.
- A Community Health Council (CHC) representative other than that of the Health Board which is a party to the contract; or, where a CHC representative is not available, another independent lay or patient representative agreed between the Health Board and the ROC.
- All Panel members must declare any conflicts of interest and must not participate in proceedings where a conflict exists.

The Local Assessment Appeal Panel is a locally established arrangement by the Health Board to support fair and transparent resolution of disputes and is not a statutory panel defined within the NHS (Ophthalmic Services) (Wales) Regulations 2023.

Frequency of Meetings and Monitoring of Outcomes

It is suggested that the Local Assessment Appeal Panel meets as required, with sufficient frequency to ensure timely consideration of appeals relating to optometry contractual breaches. In addition:

- The Panel (or a related oversight group) may meet periodically to review patterns, trends, or recurring issues arising from appeals or breaches.
- This may include cases where there is a significant risk to service continuity, patient access, or quality of care within optometry services.
- Monitoring of outcomes, implementation of recommendations, and any follow-up actions will be at the discretion of the Health Board.

Scope of Disputes

- a) This process applies to disputes relating to the interpretation, application or performance of obligations under the Regulations, Clinical Service Guidance or this Breach Process, including breach or termination matters.
- b) The Health Board may continue to address issues relating to patient safety, service delivery, or regulatory compliance while a dispute is ongoing.

Continuation of Obligations

- a) Parties must continue to meet their contractual and regulatory obligation during the dispute resolution process, unless otherwise agreed or directed.
- b) The provisions continue to apply where relevant, including where services have been suspended or terminated.

9. Supporting information: Exceptional Circumstances

An exceptional circumstance refers to an event or situation that is unexpected, unusual, or beyond an individual's or organisation's control, making it difficult or impossible to fulfil a normal obligation, or adhere to standard procedures. It is difficult to detail every single possible exceptional circumstance that may occur but below are some examples for context:

1. Medical or Personal Emergencies: Serious illness, injury, or a family emergency that prevents compliance.
2. Unforeseen Operational Disruptions: Significant and unexpected events like staff shortages, sudden closures, force majeure, or other operational issues.

The Contractor would be expected to notify the Health Board of the exceptional circumstance as soon as practically possible.

Appendix 1

General Ophthalmic Services Regulations Remedial Notice

Contractor Ref: [Name and code]

Date issued: [DATE]

Dear [Contractor],

REMEDIAL NOTICE

In accordance with the *National Health Service (Ophthalmic Services) (Wales) Regulations 2023*, contractors are required to comply with all Directions and determinations issued by the Welsh Ministers relating to the provision of primary ophthalmic services.

THE HEALTH BOARD CONSIDERS THAT THE MATTERS SET OUT BELOW INDICATE NON-COMPLIANCE WITH THE GENERAL OPHTHALMIC REGULATIONS.

As such, this remedial notice is issued in accordance with the *National Health Service (Ophthalmic Services) (Wales) Regulations 2023*.

Term of Service that has been breached: [SUB-PARAGRAPH AND TITLE]

Requirement: [CONTRACTUAL REQUIREMENTS].

[EVIDENCE TO SUPPORT].

THE CONTRACTOR MUST TAKE THE FOLLOWING ACTION WITHIN **28 DAYS** TO ADDRESS THE NON-COMPLIANCE IDENTIFIED ABOVE:

1. [AGREED ACTION]; and
2. [AGREED ACTION]

FAILURE TO ADDRESS THIS OR ANY FURTHER NON-COMPLIANCE MAY RESULT IN FURTHER ACTION IN ACCORDANCE WITH THE REGULATIONS.

This notice is deemed served on the date above. You may make representations regarding this notice in writing to [INSERT ADDRESS/EMAIL], within 28 days from the date of notice.

Print Name:

Job Title:

Signature:

Date:

Health Board logo: to be inserted

Appendix 2

General Ophthalmic Services Regulations Breach Notice

Contractor Ref: [Name and code]

Date issued: [DATE]

Dear [Contractor],

BREACH NOTICE

In accordance with the *National Health Service (Ophthalmic Services) (Wales) Regulations 2023*, contractors are required to comply with all Directions and determinations issued by the Welsh Ministers relating to the provision of primary ophthalmic services.

THE HEALTH BOARD CONSIDERS THAT YOU ARE IN BREACH OF THE GENERAL OPHTHALMIC REGULATIONS.

As such, this breach notice is issued in accordance with the *National Health Service (Ophthalmic Services) (Wales) Regulations 2023*.

Term of Service that has been breached: [SUB-PARAGRAPH AND TITLE]

Requirement: [CONTRACTUAL REQUIREMENTS].

[EVIDENCE TO SUPPORT].

YOU ARE REQUIRED TO NOT REPEAT THIS BREACH AGAIN.

FAILURE TO ADDRESS THIS BREACH OR ANY FURTHER NON-COMPLIANCE MAY RESULT IN FURTHER ACTION IN ACCORDANCE WITH THE REGULATIONS.

This notice is deemed served on the date above. If you consider that the information set out in this notice is incorrect, incomplete, or requires clarification, you may make written representations to the Health Board at [INSERT ADDRESS/EMAIL] within **28 days** of the date of this notice.

Any representations received will be considered before the Health Board determines whether further action is required.

Print Name:

Job Title:

Signature:

Date:

Appendix 3

To:

[Name of contractor / performer]

[Practice name (if applicable)]

[Practice address]

[DATE]

**RE: Notice regarding compliance with the National Health Service (Ophthalmic Services)
(Wales) Regulations 2023**

Dear [CONTRACTOR NAME],

Health Board logo: to be inserted

This letter concerns your compliance with the National Health Service (Ophthalmic Services) (Wales) Regulations 2023 and associated requirements relating to the provision of NHS ophthalmic services.

The purpose of this notice is to set out identified areas of non-compliance, explain the Local Health Board's position, and confirm any actions required and/or decisions taken.

The Local Health Board has identified the following non-compliance:

- Issue:
[Description of the issue]
- Regulatory requirement:
[Relevant regulation / Terms of Service duty]
- Evidence:
[Audit findings, claims data, inspection outcome, correspondence, etc.]
- Period covered:
[Dates or ongoing]

The following action, regarding the non-compliance, has been taken to date:

Date	Action
[date]	Initial concern identified
[date]	Remedial notice issued
[date]	Breach notice issued
[date]	Follow-up / evidence reviewed

The Health Board considers that the above matters constitute a breach of regulatory requirements. This breach is recorded on the basis that:

- the non-compliance has occurred; and
- previous opportunities to remedy have not resulted in sustained compliance.

As non-compliance has continued, the Health Board is considering taking formal enforcement action.

The actions under consideration include one or more of the following:

- imposition of conditions on inclusion in an ophthalmic or supplementary list;
- recovery and/or withholding of NHS payments;
- suspension from a list;
- removal from a list.

Before any decision is taken, you are invited to submit written representations by [date].

Representations may include:

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- evidence of compliance;
- mitigation;
- explanations or contextual factors.

If you have any questions regarding this notice, please contact:

[Name]

[Role]

[Email / phone]

Signed:

[Authorised officer name]

[Job title]

[Health Board]

Appendix 4

To:

[Name of contractor / performer]

[Practice name (if applicable)]

[Practice address]

[DATE]

**RE: Notice regarding compliance with the National Health Service (Ophthalmic Services)
(Wales) Regulations 2023**

Dear [CONTRACTOR NAME],

Health Board logo: to be inserted

This letter concerns your compliance with the National Health Service (Ophthalmic Services) (Wales) Regulations 2023 and associated requirements relating to the provision of NHS ophthalmic services.

The purpose of this notice is to set out identified areas of non-compliance, explain the Local Health Board's position, and confirm any actions required and/or decisions taken.

The Local Health Board has identified the following non-compliance:

- Issue:
[Description of the issue]
- Regulatory requirement:
[Relevant regulation / Terms of Service duty]
- Evidence:
[Audit findings, claims data, inspection outcome, correspondence, etc.]
- Period covered:
[Dates or ongoing]

The following action, regarding the non-compliance, has been taken to date:

[date]	Initial concern identified
[date]	Remedial notice issued
[date]	Breach notice issued
[date]	Follow-up / evidence reviewed

The Health Board considers that the above matters constitute a breach of regulatory requirements. This breach is recorded on the basis that:

- the non-compliance has occurred; and
- previous opportunities to remedy have not resulted in sustained compliance.

Having reviewed all available evidence and any representations received, the Health Board has decided to:

- ☐ Take no further action
- ☐ Impose conditions
- ☐ Recover / withhold payments
- ☐ Suspend from the list
- ☐ Remove from the list

Effective date: [date]

The decision has been taken because:

- the non-compliance has persisted; and/or
- remedial opportunities have not resulted in sustained compliance; and/or
- the action is proportionate to protect patients, NHS resources, and service integrity.

[TO INCLUDE IF CONDITIONS ARE IMPOSED]

The following conditions apply:

Condition	Evidence required	Review date
[Condition 1]	[Evidence]	[Date]
[Condition 2]	[Evidence]	[Date]

Failure to meet these conditions may result in further enforcement action.

You have the right to raise any dispute arising from this decision in accordance with the Dispute Resolution Process set out in the Health Board's Breach Process. Any dispute should be made in writing within 4 weeks of the date of this letter and submitted to the appropriate Executive Director of the Health Board.

If you have any questions regarding this notice, please contact:

[Name]

[Role]

[Email / phone]

Signed:

[Authorised officer name]

[Job title]

[Health Board]

Appendix 5

To:

[Name of contractor / performer]

[Practice name (if applicable)]

[Practice address]

[DATE]

RE: Notice regarding compliance with the National Health Service (Ophthalmic Services) (Wales) Regulations 2023

Dear [CONTRACTOR NAME],

Health Board logo: to be inserted

This letter concerns your compliance with the National Health Service (Ophthalmic Services) (Wales) Regulations 2023 and associated requirements relating to the provision of NHS ophthalmic services.

The purpose of this notice is to set out identified areas of non-compliance, explain the Local Health Board's position, and confirm any actions required and/or decisions taken.

The Local Health Board has identified the following non-compliance:

- Issue:
[Description of the issue]
- Regulatory requirement:
[Relevant regulation / Terms of Service duty]
- Evidence:
[Audit findings, claims data, inspection outcome, correspondence, etc.]
- Period covered:
[Dates or ongoing]

The following action, regarding the non-compliance, has been taken to date:

[date]	Initial concern identified
[date]	Remedial notice issued
[date]	Breach notice issued
[date]	Follow-up / evidence reviewed

The Local Health Board confirms that:

- the required actions have been completed; and
- no further action will be taken at this time.

Please note that any recurrence of similar non-compliance may result in immediate escalation.

If you have any questions regarding this notice, please contact:

[Name]

[Role]

Health Board logo: to be inserted

[Email / phone]

Signed:

[Authorised officer name]

[Job title]

[Health Board]