

Draft Regulations laid before Senedd Cymru under section 11(6)(c) of the NHS Redress (Wales) Measure 2008, for approval by resolution of Senedd Cymru.

DRAFT WELSH STATUTORY
INSTRUMENTS

2025 No. (W.)

**NATIONAL HEALTH
SERVICE, WALES**

**The National Health Service
(Concerns, Complaints and Redress
Arrangements) (Wales)
(Amendment) Regulations 2025**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (S.I. 2011/704 (W. 108)) (“the Principal Regulations”).

Regulation 4 amends regulation 2 of the Principal Regulations (interpretation), inserting new definitions into that provision.

Regulation 5 amends regulation 3 of the Principal Regulations (general principles for the handling and investigation of concerns), including provision for a person who notifies a concern to be kept informed of progress and time frames and about communication requirements.

Regulation 6 amends regulation 11 of the Principal Regulations (notification of concerns) to remove a cross-reference to a provision which is omitted by these Regulations.

Regulation 7 amends regulation 14 of the Principal Regulations (matters and concerns excluded from consideration under the arrangements) to add an exclusion from the scope of the Principal Regulations where the responsible body considers the concern to be vexatious or frivolous, and to provide that concerns that are resolved through the early resolution procedure are excluded from the scope of specified regulations.

Regulation 8 amends regulation 17 of the Principal Regulations (concerns involving more than one responsible body) to amend the time frames for seeking consent, from a person who notifies a concern, to notify the other responsible bodies involved, and the time frame for giving that notification.

Regulations 9 and 10 amend regulations 19 (action to be taken where a Local Health Board receives notification of a concern about services provided by a primary care provider) and 20 (action to be taken where a Local Health Board receives notification of a concern from a primary care provider) of the Principal Regulations, respectively. The amendments specify the circumstances in which primary care providers are to attempt to resolve a concern through the early resolution procedure, and not the Local Health Board.

Regulation 11 amends regulation 22 of the Principal Regulations (procedure before investigation) to add further matters for the responsible body to offer to discuss with the person notifying the concern, and further requirements where such a discussion takes place including a requirement to keep records of offers of discussions under that provision.

Regulation 12 inserts regulation 22A into the Principal Regulations, making provision regarding the early resolution period and early resolution procedure.

Regulation 13 inserts regulation 24A into the Principal Regulations, making provision to enable the suspension of the early resolution procedure or an investigation pending the outcome of a safeguarding enquiry, criminal investigation or criminal proceedings.

Regulation 14 amends regulation 26 of the Principal Regulations (response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability) to amend the time frames for providing an interim report, and an investigation report under regulation 31.

Regulation 15 amends regulation 29 of the Principal Regulations (redress – financial compensation) to increase the limit for the financial compensation element of redress for the purposes of Part 6.

Regulation 16 amends regulation 31 of the Principal Regulations (investigation report) to include a requirement for a Welsh NHS body (as defined in regulation 2(1) of the Principal Regulations) to offer to discuss an investigation report, where it has provided one, for the purposes of Part 6.

Regulation 17 amends regulation 33 of the Principal Regulations (redress – communication of a decision) to reduce the time frame within which a Welsh NHS

body must communicate a decision for the purposes of Part 6.

Regulation 18 amends regulation 40 of the Principal Regulations (response to an investigation under regulation 39 where a Welsh NHS body is of the opinion that there is, or there may be, a qualifying liability) to amend the time frames for providing an interim report, and an investigation report under regulation 46.

Regulation 19 amends regulation 44 of the Principal Regulations (redress – financial compensation) to increase the limit for the financial compensation element of redress for the purposes of Part 7.

Regulation 20 amends regulation 46 of the Principal Regulations (investigation report) to include a requirement for a Welsh NHS body to offer to discuss an investigation report, where it has provided one, for the purposes of Part 7.

Regulation 21 amends regulation 48 of the Principal Regulations (redress – communication of a decision) to reduce the time frame within which a Welsh NHS body must communicate a decision for the purposes of Part 7.

Regulation 22 amends regulation 50 of the Principal Regulations (monitoring the operation of arrangements for dealing with concerns) to add new record-keeping requirements regarding whether an offer of redress was made, and any determination that independent medical advice is not required in relation to concerns involving the death of, or moderate or severe harm to, a patient.

Regulation 23 amends regulation 51 of the Principal Regulations (annual report) to require a Local Health Board to include the annual reports of responsible bodies in its own annual report in specified circumstances.

Regulation 24 contains transitional provision.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Welsh Government, Cathays Park, Cardiff, CF10 3NQ and on the website at <https://www.gov.wales>.

Draft Regulations laid before Senedd Cymru under section 11(6)(c) of the NHS Redress (Wales) Measure 2008, for approval by resolution of Senedd Cymru.

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INSTRUMENTS

2025 No. (W.)

**NATIONAL HEALTH
SERVICE, WALES**

**The National Health Service
(Concerns, Complaints and Redress
Arrangements) (Wales)
(Amendment) Regulations 2025**

Made

Coming into force

1 April 2026

The Welsh Ministers make the following Regulations in exercise of the powers conferred by: sections 113(2), (3), 115(1), (2), (5), (6), and 195(1) of the Health and Social Care (Community Health and Standards) Act 2003⁽¹⁾; sections 1(1) to (4)(a), (5), (6), 2(1), (2), (4), (5), (6)(a), 3(1), (2)(b) to (d), 4(1), (2)(a), 5, 9(1) to (5), (7) and 11(2), (3) of the NHS Redress (Wales) Measure 2008⁽²⁾.

A draft of these Regulations was laid before, and approved by resolution of, Senedd Cymru in

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- (1) 2003 c. 43. Section 113(2)(d) of the Health and Social Care (Community Health and Standards) Act 2003 (“the 2003 Act”) was inserted by section 10 of the NHS Redress (Wales) Measure 2008 (nawm 1). Section 113(3)(b) of the 2003 Act was repealed by the following provisions of the Health and Social Care Act 2008 (c. 14): section 95 and paragraph 45 of Schedule 5; section 166 and Part 1 of Schedule 15. *See* section 148 of the 2003 Act for the definitions of “NHS body” and “Welsh NHS body”, and section 194 for the definition of “the Assembly”. Section 115(1) of the 2003 Act was amended by regulation 206 of S.I. 2016/413 (W. 131). The functions of the National Assembly for Wales are now exercisable by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 (c. 32).
- (2) 2008 nawm 1.

accordance with section 11(6)(c) of the NHS Redress (Wales) Measure 2008⁽¹⁾.

Title and coming into force

1.—(1) The title of these Regulations is the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025.

(2) These Regulations come into force on 1 April 2026.

Interpretation

2.—(1) In these Regulations, “the Principal Regulations” means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011⁽²⁾.

(2) Unless stated otherwise in these Regulations, expressions used in these Regulations have the same meaning as given in the Principal Regulations.

Amendments to the Principal Regulations

3. The Principal Regulations are amended as set out at regulations 4 to 23.

Amendment to regulation 2

4. In regulation 2(1) (interpretation), at the appropriate places insert—

““early resolution period” (“*cyfnod datrys yn gynnar*”) means a period of no longer than 10 working days beginning with the day on which the responsible body acknowledged receipt of the notification of the concern;”;

““early resolution procedure” (“*gweithdrefn datrys yn gynnar*”) means the steps required to be taken by a responsible body in accordance with regulation 22A to attempt to resolve the concern to the satisfaction of the person who notified the concern without

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- (1) See also section 40 of the Legislation (Wales) Act 2019 (anaw 4) for provision about the procedure that applies to this instrument. The reference in section 11(6) of the NHS Redress (Wales) Measure 2008 to the National Assembly for Wales now has effect as a reference to Senedd Cymru, by virtue of section 150A(2) of the Government of Wales Act 2006. The reference to either House of Parliament in section 195(6) of the 2003 Act is to be read as a reference to Senedd Cymru by virtue of sections 150A(2) and 162(1) of, and paragraph 34(1) and (2) of Schedule 11 to, the Government of Wales Act 2006.
- (2) S.I. 2011/704 (W. 108), amended by S.I. 2011/1706 (W. 192), S.I. 2013/235, S.I. 2022/634, S.I. 2023/274 (W. 41), S.I. 2023/281 (W. 42), S.I. 2023/1053 (W. 179) and S.I. 2023/1071.

proceeding to an investigation under regulation 23;”;

““in-person communication” (*“cyfathrebu uniongyrchol”*) means communication that is made by telephone call, audio-visual communication or a face-to-face meeting;”.

Amendment to regulation 3

5.—(1) Regulation 3(1) (general principles for the handling and investigation of concerns) is amended as follows.

(2) After sub-paragraph (h) insert—

“(ha) persons who notify concerns are kept informed of the progress of the investigation in relation to the concern and the likely time frame for completing that investigation;”.

(3) After sub-paragraph (j) omit “and” and insert—

“(ja) any communication with persons who notify concerns—

- (i) as far as reasonably possible, is provided in a manner that the person who notified the concern can understand;
- (ii) where appropriate, provides an explanation of legal or medical terms;
- (iii) as far as reasonably possible, is provided in the manner in which the person who notified the concern has requested; and”.

Amendment to regulation 11

6. At the beginning of regulation 11(2) (notification of concerns), for “Subject to regulation 14(1)(f), where” substitute “Where”.

Amendment to regulation 14

7.—(1) Regulation 14 (matters and concerns excluded from consideration under the arrangements) is amended as follows.

(2) In paragraph (1)—

- (a) omit sub-paragraph (f);
- (b) in sub-paragraph (g), for “sub-paragraph (f)” substitute “paragraph (5)”;
- (c) after sub-paragraph (h) insert—

“(ha) a concern which the responsible body considers is vexatious or frivolous;”.

(3) At the beginning of paragraph (2), for “Subject to paragraph (3), where” substitute “Where”.

(4) Omit paragraph (3).

(5) After paragraph (4) insert—

“(5) A concern which is resolved during the early resolution period in accordance with the early resolution procedure is excluded from the scope of the arrangements required under regulations 23 to 48.”

Amendment to regulation 17

8. Regulation 17(2) (concerns involving more than one responsible body) is amended as follows—

- (a) in sub-paragraph (a), for the words from “within two” to “of the concern” substitute “not later than five working days after the day on which it receives notification of the concern”;
- (b) in sub-paragraph (b), for “within two working days of receipt of” substitute “not later than two working days after the day on which it receives”.

Amendment to regulation 19

9.—(1) Regulation 19 (action to be taken where a Local Health Board receives notification of a concern about services provided by a primary care provider) is amended as follows.

(2) At the beginning of paragraph (1), for “When a” substitute “Subject to paragraph (5), when a”.

(3) After paragraph (4) insert—

“(5) If the person notifying the concern has consented to the responsible body attempting to resolve the concern during the early resolution period in accordance with regulation 22A, the primary care provider is the responsible body who must attempt to resolve the concern during the early resolution period, not the Local Health Board, unless exceptional circumstances apply.”

Amendment to regulation 20

10.—(1) Regulation 20 (action to be taken where a Local Health Board receives notification of a concern from a primary care provider) is amended as follows.

(2) At the beginning of paragraph (1), for “When a” substitute “Subject to paragraph (5), when a”.

(3) After paragraph (4) insert—

“(5) If the person notifying the concern has consented to the responsible body attempting to resolve the concern during the early resolution period in accordance with regulation 22A, the primary care provider is the responsible body who must attempt to resolve the concern during

the early resolution period, not the Local Health Board, unless exceptional circumstances apply.”

Amendment to regulation 22

11.—(1) Regulation 22 (procedure before investigation) is amended as follows.

(2) In paragraph (1), omit “14(1)(f) or”.

(3) At the end of paragraph (4)(c)(ii), omit the full stop and insert—

“;

- (d) the resolution or outcome they desire in relation to the concern they have notified;
- (e) their understanding of, and perspective on, the facts and circumstances of the concern they have notified;
- (f) the person’s preferred method of communication and whether they have any specific communication requirements;
- (g) except where an investigation under regulation 23 has begun in relation to the concern, the early resolution procedure, including—
 - (i) whether the responsible body considers that the early resolution procedure is appropriate in the circumstances, and
 - (ii) if the responsible body considers that the early resolution procedure is not appropriate (for example due to complexity or severity), the reason for this;
- (h) that an assessment of whether a qualifying liability exists in relation to the concern notified can only take place where an investigation under regulation 23 is undertaken;
- (i) where the responsible body considers that the early resolution period is appropriate in the circumstances, whether the person who notified the concern consents to the responsible body attempting to resolve the concern in accordance with the early resolution procedure.”

(4) After paragraph (4) insert—

“(4A) Where the person who notified the concern accepts the offer of a discussion under paragraph (4), such discussion must be by in-person communication.

(4B) Where the responsible body is notified that any services mentioned in paragraph (4)(b) are required by the person who notified the concern, when arranging a discussion under paragraph (4), the responsible body must take into account the need to ensure that such services are provided at that discussion.

(4C) The responsible body must keep a record of—

- (a) whether or not the offer of a discussion under paragraph (4) is accepted, and
- (b) if the offer is accepted, the matters discussed.”

Insertion of regulation 22A

12. After regulation 22 (procedure before investigation) insert—

“Early resolution period and early resolution procedure

22A.—(1) This regulation applies where—

- (a) a person who has notified a concern has given consent (in the course of a discussion under regulation 22(4) or under paragraph (2)) to the responsible body attempting to resolve the concern during the early resolution period in accordance with the early resolution procedure set out in this regulation, and
- (b) the responsible body considers that the early resolution procedure is appropriate in the circumstances.

(2) Where a discussion under regulation 22(4) has not taken place, the responsible body must seek confirmation from the person who notified the concern whether they consent to the responsible body attempting to resolve the concern during the early resolution period before taking any steps under paragraph (3).

(3) The responsible body must take such steps as it considers appropriate to attempt to resolve the concern to the satisfaction of the person who notified the concern during the early resolution period before proceeding to undertake an investigation under regulation 23.

(4) Where the responsible body has attempted resolution during the early resolution period, the responsible body must, as soon as reasonably possible—

- (a) seek confirmation from the person who notified the concern as to whether or not the concern has been resolved to

- their satisfaction during the early resolution period;
- (b) where the person who notified the concern confirms that the concern has been resolved to their satisfaction, provide written confirmation to the person who notified the concern that the early resolution procedure has concluded and the concern will not be investigated under regulation 23;
 - (c) where the person who notified the concern confirms that the concern has not been resolved to their satisfaction—
 - (i) begin investigating the concern under regulation 23, and
 - (ii) provide written confirmation to the person to that effect;
 - (d) where the person who notified the concern does not provide confirmation under sub-paragraph (a), and the responsible body has taken all reasonable steps to communicate with that person for that purpose—
 - (i) if the responsible body considers that the concern has been resolved during the early resolution period, provide written confirmation in accordance with sub-paragraph (b), or
 - (ii) if the responsible body considers that the concern has not been resolved during the early resolution period, take the steps specified in sub-paragraph (c)(i) and (ii);
 - (e) keep a record of the outcome of the early resolution procedure.”

Insertion of regulation 24A

13. After regulation 24 (response) insert—

“Suspension of early resolution procedure or an investigation

24A.—(1) Where the responsible body becomes aware of a safeguarding enquiry, criminal investigation or criminal proceedings in relation to a matter which is the subject of a concern that has been notified to the responsible body, the responsible body may suspend the early resolution procedure or an investigation under these Regulations, in relation to the concern.

(2) A suspension under paragraph (1) may be for such period as the responsible body considers necessary to allow for the completion of any safeguarding enquiry or criminal investigation, or the determination of any criminal proceedings.

(3) When determining the period under paragraph (2), the responsible body must have regard to—

- (a) any requests by those persons responsible for undertaking the safeguarding enquiry, criminal investigation or criminal proceedings to suspend the early resolution procedure or an investigation under these Regulations, or
- (b) any consent provided by those persons responsible for undertaking the safeguarding enquiry, criminal investigation or criminal proceedings to proceed with the early resolution procedure or an investigation under these Regulations.

(4) Subject to paragraph (6), where the responsible body has suspended the early resolution procedure or an investigation under paragraph (1), the responsible body must give notice in writing to the person who notified the concern that the early resolution procedure or investigation of the concern has been suspended, pending the completion of a safeguarding enquiry or criminal investigation, or the determination of criminal proceedings, as the case may be.

(5) A notice under paragraph (4) must be given not later than two working days after the day on which the responsible body becomes aware of the safeguarding enquiry, criminal investigation or criminal proceedings.

(6) These Regulations do not permit or require a responsible body to disclose any information which would—

- (a) prejudice any criminal investigation, criminal proceedings or prosecution, or
- (b) contravene any restriction on disclosure arising by virtue of an enactment or rule of law.

(7) In this regulation, “safeguarding enquiry” means a process undertaken by a local authority to enable the local authority to decide—

- (a) whether any action should be taken and, if so, what and by whom, in relation to an adult at risk under section

126 of the Social Services and Well-being (Wales) Act 2014⁽¹⁾;

- (b) whether they should take any action to safeguard or promote the welfare of a child under section 47 of the Children Act 1989⁽²⁾.”

Amendment to regulation 26

14.—(1) Regulation 26 (response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability) is amended as follows.

(2) In paragraph (3)(b), for “six months” substitute “120 working days”.

(3) In paragraph (4), for “six month” substitute “120 working day”.

(4) In paragraph (5), for “twelve months” substitute “120 working days”.

(5) In paragraph (6), for “twelve month” substitute “120 working day”.

(6) After paragraph (6) insert—

“(7) The Welsh NHS body may provide an interim report at the same time as an investigation report referred to in regulation 31 where the investigation report is ready to be provided to the person who notified the concern before the interim report has been provided.

(8) Where the interim report and investigation report are provided at the same time—

- (a) the Welsh NHS body is not required to provide the information in paragraph (1)(c) and (h), and
- (b) paragraph (1)(g) is to be read as if for “which will be” there were substituted “that was”.”

(1) 2014 anaw 4. *See* section 126(1) for the definition of “adult at risk”.

(2) 1989 c. 41. Section 47 was amended by the following enactments: the Health Authorities Act 1995 (c. 17) (section 2 and paragraph 118 of Schedule 1); the Health and Social Care (Community Health and Standards) Act 2003 (c. 43) (section 34 and paragraph 79 of Schedule 4); the Children Act 2004 (c. 31) (section 53(3)); S.I. 2007/961 (W. 85) (article 3 and paragraph 20 of the Schedule); Policing and Crime Act 2009 (c. 26) (section 112(2) and Part 13 of Schedule 8); S.I. 2010/1158 (article 5(1) and paragraph 37(8) of Schedule 2, article 5(2) and Part 2 of Schedule 3); Health and Social Care Act 2012 (c. 7) (section 55(2) and paragraph 53 of Schedule 5); S.I. 2016/413 (W. 131) (regulation 100); S.I. 2022/744 (W. 161) (regulation 4 and paragraph 1(2) of Schedule 2); the Health and Care Act 2022 (c. 31) (section 1(2) and paragraph 1 of Schedule 1, section 32 and paragraph 33 of Schedule 4).

Amendment to regulation 29

15. In regulation 29(1) and (2) (redress – financial compensation), for “£25,000” substitute “£50,000”.

Amendment to regulation 31

16. In regulation 31 (investigation report), for paragraph (3) substitute—

“(3) Unless paragraph (4) applies, the Welsh NHS body must—

- (a) provide the person who is seeking redress under this Part, or their legal representative, with a copy of the investigation report within the time frame set out in regulation 26(5) or (6), and
- (b) offer the person who is seeking redress under this Part an opportunity to discuss that investigation report with the responsible officer or a person acting on the responsible officer’s behalf, by way of in-person communication.”

Amendment to regulation 33

17. In regulation 33(a) (redress – communication of a decision)—

- (a) for “twelve months” substitute “120 working days”;
- (b) for “twelve month” substitute “120 working day”.

Amendment to regulation 40

18.—(1) Regulation 40 (response to an investigation under regulation 39 where a Welsh NHS body is of the opinion that there is, or there may be, a qualifying liability) is amended as follows.

(2) In paragraph (3)(b), for “six months” substitute “120 working days”.

(3) In paragraph (4), for “six month” substitute “120 working day”.

(4) In paragraph (5), for “twelve months” substitute “120 working days”.

(5) In paragraph (6), for “twelve month” substitute “120 working day”.

Amendment to regulation 44

19. In regulation 44(1) (redress – financial compensation), for “£25,000” substitute “£50,000”.

Amendment to regulation 46

20. In regulation 46 (investigation report), for paragraph (3) substitute—

“(3) Unless paragraph (4) applies, the Welsh NHS body must—

- (a) provide the person who is seeking redress under this Part, or their legal representative, with a copy of the investigation report within the time frame set out in regulation 40(5) or (6), and
- (b) offer the person who is seeking redress under this Part an opportunity to discuss that investigation report with the responsible officer or a person acting on the responsible officer’s behalf, by way of in-person communication.”

Amendment to regulation 48

21. Regulation 48(a) (redress – communication of a decision) is amended as follows—

- (a) for “twelve months” substitute “120 working days”;
- (b) for “twelve month” substitute “120 working day”.

Amendment to regulation 50

22.—(1) Regulation 50 (monitoring the operation of arrangements for dealing with concerns) is amended as follows.

(2) After paragraph (a) insert—

“(aa) where the concern involves the death of, or moderate or severe harm to, a patient, and the responsible body determines that independent medical advice is not required for the purposes of investigating the matters raised by the concern for the purposes of regulation 23(1)(e), the reason for that determination;”.

(3) In paragraph (b), after “each concern” insert “including, where a qualifying liability was found to exist, whether an offer of redress was made”.

Amendment to regulation 51

23. After paragraph (3) of regulation 51 (annual report) insert—

“(4) A Local Health Board’s annual report for a year, prepared under paragraph (1), must include a copy of each annual report, for that

year, of the responsible bodies listed under paragraph (2), that was provided to it under paragraph (3).”

Transitional provision

24. These Regulations do not apply to any concern notified in accordance with arrangements in place under the Principal Regulations before the date on which these Regulations come into force.

Name

Cabinet Secretary for Health and Social Care, one of the Welsh Ministers

Date