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WELSH STATUTORY INSTRUMENTS

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**2011 No. 704**

**The National Health Service (Concerns, Complaints  
and Redress Arrangements) (Wales) Regulations 2011**

**PART 5**

**HANDLING AND INVESTIGATION OF CONCERNS**

**Procedure before investigation**

**22.**—(1) Except where regulation 14(1)(f) or 18 applies, a responsible body must acknowledge receipt of the notification of the concern not later than two working days after the day on which it receives it.

(2) The acknowledgement may be made in writing or electronically, depending upon how the concern was notified.

(3) Where a concern was notified verbally, the acknowledgement must be in writing.

(4) At the time it acknowledges notification of a concern, the responsible body must offer to discuss with the person who notified the concern, at a time to be agreed with that person—

- (a) the manner in which the investigation of the concern will be handled, including consent to the use of medical records;
- (b) the availability of advocacy and support services which may be of assistance to that person in their pursuit of the concern;
- (c) the period within which—
  - (i) the investigation of the concern is likely to be completed; and
  - (ii) the response required by regulation 24 is likely to be sent to that person.

(5) If the person who notifies the concern does not accept the offer of a discussion under paragraph (4), the responsible body must consider and make a decision upon the matters set out in sub-paragraphs (a) to (c) of that paragraph and write to the person accordingly.

(6) The responsible body must send a copy of the notification of a concern to any person who is the subject of that concern unless—

- (a) this has already been done; or
- (b) provision of a copy of the notification to such a person at that time would, in the reasonable opinion of the responsible body, prejudice its consideration of the matters raised by the concern.

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**Commencement Information**

**II** Reg. 22 in force at 1.4.2011, see [reg. 1\(2\)](#)

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*Changes to legislation:* There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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## Investigation of concerns

**23.**—(1) The responsible body must investigate the matters raised in the notification of a concern in the manner which appears to that body to be most appropriate to reach a conclusion in respect of those matters thoroughly, speedily and efficiently, having particular regard to—

- (a) the carrying out of an initial assessment of the concern to assist in its determination of the depth and the parameters of the investigation required and keeping this determination under review;
- (b) the method and timing of communication with the person who notified or who is affected by the concern;
- (c) the most appropriate method of involving the person who notified the concern with the investigation, including discussion about how the investigation is conducted;
- (d) the level and type of support required by any member or members of the staff of the responsible body who are involved in the matters raised by the concern;
- (e) whether the person investigating the matters raised by the concern requires independent medical or other advice;
- (f) whether the concern may be capable of resolution by making use of alternative dispute resolution;
- (g) the making of decisions about the root cause of the matters giving rise to the notification of the concern;
- (h) any guidance issued by the Welsh Ministers with respect to the exercise of the responsible body's functions; and
- (i) where the responsible body is a Welsh NHS body and the concern notified includes an allegation that harm has or may have been caused—
  - (i) the likelihood of any qualifying liability arising;
  - (ii) the duty to consider redress in accordance with regulation 25; and
  - (iii) where appropriate, consideration of the additional requirements set out in Part 6.

(2) Where a concern has been notified to a Local Health Board by or about a primary care provider in accordance with regulation 13(1)(d) and regulation 18, the Local Health Board must not consider the matters in paragraph (1)(i).

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### Commencement Information

**I2** Reg. 23 in force at 1.4.2011, see [reg. 1\(2\)](#)

## Response

**24.**—(1) Unless regulation 26 applies and a responsible body that is a Welsh NHS body produces an interim report in accordance with that regulation, a responsible body must prepare a written response to the matter or matters raised in a concern which has been investigated in accordance with arrangements for dealing with concerns under these Regulations which—

- (a) summarises the nature and substance of the matter or matters raised in the concern;
- (b) describes the investigation undertaken in accordance with regulation 23;
- (c) contains copies of any expert opinions that the person investigating the concern has received during the investigation;
- (d) contains a copy of any relevant medical records, where this is appropriate;
- (e) where appropriate, contains an apology;

- (f) identifies what action, if any, will be taken in light of the outcome of the investigation;
  - (g) contains details of the right to notify the concern to the Public Services Ombudsman for Wales;
  - (h) offers the person notifying the concern the opportunity to discuss the contents of the response with the responsible officer or a person acting on his or her behalf; and
  - (i) is signed by the responsible officer or a person acting on his or her behalf.
- (2) In respect of a concern which includes an allegation that harm has or may have been caused, a responsible body that is a Welsh NHS body must, if it is of the view that there is no qualifying liability give reasons in the response for this decision.
- (3) A responsible body must take all reasonable steps to send a response to the person who notified the concern within thirty working days beginning on the day upon which it received notification of the concern.
- (4) If a responsible body is unable to provide a response within thirty working days in accordance with paragraph (3), it must—
- (a) notify the person who notified the concern accordingly and explain the reason why; and
  - (b) send the response as soon as reasonably practicable and within six months beginning on the day upon which it received notification of the concern.
- (5) If exceptional circumstances mean that the six month period in paragraph (4)(b) cannot be adhered to, the responsible body must advise the person who notified the concern of the reasons for the delay and when a response may be expected.

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**Commencement Information**

**I3** Reg. 24 in force at 1.4.2011, see [reg. 1\(2\)](#)

**Changes to legislation:**

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. Any changes that have already been made by the team appear in the content and are referenced with annotations.

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**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- reg. 3(1) reg. 3 renumbered as reg. 3(1) by [S.I. 2023/281 reg. 2\(3\)\(a\)](#)
- reg. 3(2)(3) inserted by [S.I. 2023/281 reg. 2\(3\)\(b\)](#)
- reg. 14(1)(k) and word inserted by [S.I. 2023/281 reg. 2\(5\)\(e\)](#)
- reg. 22(7) inserted by [S.I. 2023/274 reg. 14\(5\)\(c\)](#)
- reg. 34(1)(ca)-(cc) inserted by [S.I. 2013/235 Sch. 2 para. 162\(1\)\(b\)](#)
- reg. 34(1)(ca)-(cc) inserted by [S.I. 2013/235 Sch. 2 para. 162\(2\)\(b\)](#)
- reg. 34(1)(ca) substituted by [S.I. 2022/634 reg. 52\(2\)](#)
- reg. 34(1)(ca) substituted by [S.I. 2022/634 reg. 53\(2\)](#) (Amendment to Welsh text)