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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 7**

**REQUIREMENT FOR NHS BODIES, OTHER THAN WELSH NHS BODIES,  
TO CONSIDER REDRESS AND PROCEDURE TO BE FOLLOWED BY  
A WELSH NHS BODY WHEN IT RECEIVES NOTIFICATION OF A  
CONCERN IN ACCORDANCE WITH THE PROVISIONS OF THIS PART**

**Interpretation of this Part**

- 34.**—(1) For the purposes of this Part, “an English NHS body” (*“corff GIG Lloegr”*) means—
- (a) a Strategic Health Authority, established under section 13 of the National Health Service Act 2006<sup>(1)</sup>;
  - (b) a Primary Care Trust, established under section 18 of the National Health Service Act 2006;
  - (c) an NHS Trust, established under section 25 of the National Health Service Act 2006;
  - (d) a Special Health Authority, established under section 28 of the National Health Service Act 2006; or
  - (e) an NHS Foundation Trust authorised under Chapter 5 of the National Health Service Act 2006,

that is providing, or arranging for the provision of, services whose provision is the subject of arrangements with a Welsh NHS body.

- (2) For the purposes of this Part, “a Scottish NHS body” (*“corff GIG yr Alban”*) means—
- (a) a Health Board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978<sup>(2)</sup>;
  - (b) a Special Health Board constituted under section 2(1)(b) of the National Health Service (Scotland) Act 1978; or
  - (c) the Common Services Agency constituted under section 10 of the National Health Service (Scotland) Act 1978,

providing, or arranging for the provision of services whose provision is the subject of arrangements with a Welsh NHS body.

- (3) For the purposes of this Part, “a Northern Irish NHS body” (*“corff GIG Gogledd Iwerddon”*) means—

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(1) 2006 c. 41.  
(2) 1978 c. 29.

- (a) a Health and Social Services Trust established under the Health and Personal Social Services (Northern Ireland) Order 1991<sup>(3)</sup>;
- (b) the Regional Health and Social Care Board established under the Health and Social Care (Reform) Act (Northern Ireland) 2009<sup>(4)</sup>;
- (c) the Northern Ireland Blood Transfusion Service established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990<sup>(5)</sup>;
- (d) the Regional Business Services Organisation established under the Health and Social Care (Reform) Act (Northern Ireland) 2009; or
- (e) the Regional Agency for Public Health and Social Well-Being established under the Health and Social Care (Reform) Act (Northern Ireland) 2009,

providing or arranging for the provision of services whose provision is the subject of arrangements with a Welsh NHS body.

(4) “Relevant complaints procedure” (“*gweithdrefn gwynion berthnasol*”) means a complaints procedure that an English NHS body must follow on receipt of a concern.

(5) “Person who notified a concern” (“*person a ddatganodd bryder*”) means, depending on the context, the person who notified a concern to an English NHS body, a Scottish NHS body or a Northern Irish NHS body.

### **Circumstances in which an English NHS body must consider whether or not redress may apply**

**35.** If an English NHS body receives notification of a concern which includes an allegation that harm has or may have been caused under a relevant complaints procedure that relates to services which it has provided, or arranged for the provision of, under arrangements with a Welsh NHS body, that English NHS body must, when considering the concern in accordance with that complaints procedure, give consideration to whether or not the concern involves a qualifying liability for which redress may be available.

### **Steps to be taken where an English NHS body considers that a qualifying liability exists or may exist**

**36.—**(1) If an English NHS body concludes that such a qualifying liability exists or may exist and that redress may be available, that English NHS body must, as soon as reasonably possible, take the steps outlined in paragraph (2).

(2) The English NHS body must notify the Welsh NHS body with whom it has entered into an arrangement that it is of the view that a qualifying liability exists or may exist and, after securing any appropriate consents, provide the Welsh NHS body with the following:

- (a) a copy of the response to any concern provided in accordance with a relevant complaints procedure;
- (b) a copy of any relevant medical records;
- (c) a copy of any expert opinion that has been obtained during the investigation of a concern;
- (d) a written account of why it believes that there is or there may be a qualifying liability;
- (e) the date that it received the concern; and
- (f) such other information or assistance as the Welsh NHS body may reasonably require.

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(3) S.I.1991/194 (N.I.1).

(4) 2009 c. 1.

(5) S.I. 1990/247 (N.I. 3).

**Action to be taken by a Welsh NHS body on receipt of a notification from an English NHS body in accordance with regulation 36**

37.—(1) A Welsh NHS body must within five working days acknowledge receipt of the notification made in accordance with regulation 36.

(2) It must also, within five working days of receipt of the notification, advise the person who notified the concern to the English NHS body that the concern has been passed to it to consider whether or not a qualifying liability exists.

(3) A Welsh NHS body must determine whether or not a qualifying liability exists and it must determine whether or not an offer of redress should be made to the patient.

**Action to be taken by a Welsh NHS body on receipt of a notification from a Scottish NHS body or a Northern Irish NHS body**

38.—(1) A Welsh NHS body must, within five working days of receipt of a notification from a Scottish NHS body or a Northern Irish NHS body acknowledge receipt of the notification.

(2) It must also, within five working days of receipt of the notification, advise the person who notified the concern that the concern has been passed to it to consider whether or not a qualifying liability exists.

(3) A Welsh NHS body must determine whether or not a qualifying liability exists and it must determine whether or not an offer of redress should be made to the patient.

**Duty of Welsh NHS body to conduct an investigation**

39.—(1) On receipt of a notification from an English NHS body, a Scottish NHS body or a Northern Irish NHS body, a Welsh NHS body must—

- (a) offer to meet with the person who notified the concern; and
- (b) undertake an investigation that follows the principles in regulation 23(1)(a), (b), (c), (e), and (h).

(2) On receipt of a notification from an English NHS body, a Welsh NHS body and the English NHS body must co-operate, in a way which satisfies the relevant requirements of this Part—

- (a) to determine whether or not a qualifying liability exists; and
- (b) if it is determined that a qualifying liability exists, to make an offer of redress.

**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**

40.—(1) Where following an investigation under regulation 39 a Welsh NHS body considers that there is or there may be a qualifying liability it must produce an interim report which—

- (a) summarises the nature and substance of the matter or matters notified in the concern;
- (b) describes the investigation undertaken in accordance with regulation 39;
- (c) describes why, in the opinion of the Welsh NHS body, there is or there may be a qualifying liability;
- (d) contains a copy of any relevant medical records;
- (e) explains the availability of access to legal advice without charge in accordance with the provisions of regulation 47;
- (f) explains the availability of advocacy and support services which may be of assistance;

- (g) explains the procedure which will be followed to determine whether or not a qualifying liability exists and the procedure for making an offer of redress if such a qualifying liability is found to exist;
  - (h) confirms that, when prepared, a copy of the investigation report referred to in regulation 46 will be made available, in accordance with the provisions of that regulation, to the person who is seeking redress, or to his or her legal representative;
  - (i) contains details of the right to notify the concern, in relation to the actions or omissions of the Welsh NHS body, to the Public Services Ombudsman for Wales;
  - (j) offers the person who is seeking redress the opportunity to discuss the contents of the interim report with the responsible officer, designated in accordance with regulation 7, or a person acting on his or her behalf; and
  - (k) is signed by the responsible officer or a person acting on his or her behalf.
- (2) Save where paragraph (3) applies, a Welsh NHS body must take all reasonable steps to send an interim report to the person who notified the concern within fifty working days beginning with the day on which it received notification of the concern.
- (3) If a Welsh NHS body is not able to provide an interim report in accordance with paragraph (2), it must—
- (a) notify the person who notified the concern accordingly and explain the reason why; and
  - (b) send the interim report as soon as reasonably practicable and within six months beginning with the day upon which it received notification of the concern.
- (4) If exceptional circumstances mean that the six month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern of the reasons for the delay and when the interim report may be expected.
- (5) The investigation report referred to in regulation 46 must be provided to the person who notified the concern, or his or her legal representative, as soon as reasonably practicable and not later than twelve months from the date that the Welsh NHS body received notification of the concern.
- (6) If exceptional circumstances mean that the twelve month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern, or his or her legal representative, of the reasons for the delay and when the investigation report may be expected.

**Response to an investigation under regulation 39 where a Welsh NHS body decides that there is no qualifying liability**

41. Where following an investigation in accordance with regulation 39, a Welsh NHS body decides that the concern notified in accordance with regulation 36 or by a Scottish NHS body or Northern Irish NHS body does not involve a qualifying liability, the Welsh NHS body must—
- (a) advise, in writing, the person who notified the concern of its decision and the reasons for its decision;
  - (b) offer to meet the person who notified the concern to discuss the decision;
  - (c) provide the person who notified the concern with details of the right to notify any concern about acts or omissions of the Welsh NHS body to the Public Services Ombudsman for Wales; and
  - (d) send a copy of the decision letter in paragraph (a) to the English NHS body, the Scottish NHS body or the Northern Irish NHS body.

**Form of redress**

- 42.—(1) Redress under this Part comprises—

- (a) the making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of a qualifying liability;
- (b) the giving of an explanation;
- (c) the making of a written apology; and
- (d) the giving of a report on the action which has been, or will be, taken to prevent similar cases arising.

(2) The compensation that may be offered in accordance with regulation 42(1)(a) can take the form of entry into a contract to provide care or treatment or of financial compensation, or both.

### **Availability of Redress**

**43.**—(1) Redress is not available in relation to a liability that is or has been the subject of civil proceedings.

(2) If such civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress in accordance with this Part must cease and the Welsh NHS body must advise the person who notified the concern and the English NHS body, Scottish NHS body or Northern Irish NHS body that notified the concern to the Welsh NHS body accordingly.

### **Redress — financial compensation**

**44.**—(1) A Welsh NHS body may make an offer of redress for a qualifying liability by way of financial compensation not exceeding £25,000.

(2) Where a Welsh NHS body considers that the value to be attributed to the qualifying liability arising from the provision of qualifying services exceeds the limit set out in paragraph (1), redress in the form of financial compensation must not be offered in accordance with these Regulations.

(3) The assessment of damages for pain, suffering and loss of amenity is calculated on the common law basis. Welsh Ministers may from time to time issue a compensation tariff.

(4) If a tariff is issued in accordance with paragraph (3), it is to be used for the purpose of guidance by Welsh NHS bodies when considering the amount of financial compensation to be offered in accordance with this Part.

### **Suspension of the limitation period**

**45.**—(1) During the period in which a liability is the subject of an application for redress under this Part, any limitation period for the bringing of civil proceedings in respect of that liability which is prescribed by or under the Limitation Act 1980<sup>(6)</sup> or any other enactment is suspended and time will not run for the purposes of calculating any time limits prescribed by these enactments.

(2) For the purposes of this Part, a liability is to be considered as being the subject of an application for redress—

- (a) beginning with the date on which the initial concern which became an application for redress was received by an English NHS body, a Scottish NHS body or a Northern Irish NHS body;
- (b) subject to paragraphs (3), (4) and (5), up to and including the time when an offer of financial compensation made in accordance with regulation 48 is accepted by a patient or his or her representative by signing a formal agreement and legal waiver in accordance with regulation 48(e) or until such time as an offer of such compensation is rejected by a patient or his or her representative.

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(6) 1980 c. 58.

(3) A liability will no longer be considered a subject of an application for redress nine calendar months from the date upon which the Welsh NHS body makes an offer of financial compensation in respect of that liability.

(4) In cases where court approval of a settlement proposed by an offer is required, such as in circumstances outlined in regulation 48(f), limitation, if limitation is an issue, is suspended until a settlement is reached which receives the approval of the court.

(5) In cases where a Welsh NHS body indicates, in accordance with regulation 48, that it has decided that there is no qualifying liability and has decided not to make an offer of redress, a liability will not be considered to be the subject of an application for redress nine calendar months from the date on which the Welsh NHS body communicated its decision in accordance with regulation 48.

### **Investigation report**

**46.**—(1) A Welsh NHS body must ensure that the findings of the investigation of a concern in which a person is seeking redress under this Part are recorded in an investigation report.

(2) An investigation report will include the following—

- (a) a copy of any medical evidence that has been commissioned in accordance with this Part in order to determine whether there is a qualifying liability or which has been commissioned to determine condition and prognosis;
- (b) a statement by the Welsh NHS body confirming whether or not, in its opinion, there is a qualifying liability; and
- (c) an explanation for the opinion expressed in sub-paragraph (b).

(3) Unless paragraph (4) applies, the Welsh NHS body must provide the person who is seeking redress under this Part, or his or her legal representative, with a copy of the investigation report within the time frame set out in regulation 40(5) or (6).

(4) No copy of the investigation report need be provided by the Welsh NHS body—

- (a) before an offer of redress under this Part is made;
- (b) before a decision not to make an offer of redress is communicated;
- (c) if the investigation of redress in accordance with this Part is for any reason terminated; or
- (d) where the report contains information likely to cause the patient or other applicant for redress significant harm or distress.

### **Legal advice and instruction of medical experts**

**47.**—(1) Where a Welsh NHS body has determined that a qualifying liability exists, or may exist, in accordance with regulation 40 and this Part, the Welsh NHS body must ensure—

- (a) that legal advice is available to a person seeking redress under this Part in accordance with the following provisions of this regulation; and
- (b) if a medical expert or experts need to be instructed that such instruction is carried out jointly by the Welsh NHS body and the person who notified the concern.

(2) Legal advice must only be sought from firms of solicitors who have a recognised expertise in the field of clinical negligence. Firms will be recognised as having the necessary expertise if they have at least one partner or employee who is a member of the Law Society Clinical Negligence Panel (7) or the Action Against Medical Accidents Clinical Negligence Panel (8).

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(7) The Law Society runs an accreditation scheme for solicitors and Fellows of the Institute of Legal Executives (FILEX) who specialise in clinical negligence cases. Solicitors and FILEX who are able to demonstrate, in accordance with the Law Society's published procedure, that they are sufficiently expert in clinical negligence matters are eligible to be listed as a member of the Law Society Clinical Negligence Panel.

(3) A Welsh NHS body must ensure that legal advice without charge is available to the person who notified the concern in relation to the following matters—

- (a) the joint instruction of medical experts, including the seeking of clarification from such experts of issues arising from their reports;
- (b) any offer that is made in accordance with this Part;
- (c) any refusal to make such an offer; and
- (d) any settlement agreement that is proposed.

(4) Subject to any rights that a Welsh NHS body has to recover such expenditure from an English NHS body, the cost of such legal advice and costs arising from the instruction of such medical experts must be borne in their entirety by the Welsh NHS body.

### **Redress — communication of a decision**

**48.** Where a Welsh NHS body decides to make an offer of redress by way of financial compensation or entry into a contract to provide care or treatment or both or determines that it will not make an offer of redress on the basis that there is no qualifying liability, it must—

- (a) send the offer or the notification of the decision not to make an offer to the person who notified the concern within twelve months of the date on which the concern was notified to the Welsh NHS body. If exceptional circumstances mean that the twelve month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern, or his or her legal representative, of the reasons for the delay and when a decision in respect of the application for redress will be made;
- (b) advise that person or his or her legal representative that he or she must respond to the offer of settlement or a decision not to make an offer of settlement within six months of the date that it is made;
- (c) subject to paragraph (d), advise that if, as a result of exceptional circumstances, it will not be possible to respond to the offer of settlement or the decision not to make an offer of settlement within six months, the Welsh NHS body must be advised of the reasons for the delay in responding and when a response will be submitted;
- (d) advise a person or his or her legal representative that if an extension of time is sought to respond to an offer of settlement or a decision not to make an offer of settlement, a response is required within nine calendar months of the date of the offer as that is the time when, in accordance with regulation 45(3) and (5), limitation starts to run;
- (e) advise, if an offer is made, that the settlement proposed by the offer will be by way of a formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates;
- (f) advise that, in appropriate circumstances, the settlement agreement proposed will be subject to approval by a court in cases such as those where the person to whom the qualifying liability relates—
  - (i) is a child; or
  - (ii) lacks capacity within the meaning of the Mental Capacity Act 2005(9); and
- (g) advise that where court approval of a settlement is required, that the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

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(8) Action Against Medical Accidents (AVMA) is a charity established to promote patient safety. It runs an accreditation scheme for solicitors and Fellows of the Institute of Legal Executives (FILEX). Solicitors and FILEX who can demonstrate that they meet AVMA's published criteria for demonstrating expertise in the field of clinical negligence can become members of AVMA's Clinical Negligence Panel.

(9) 2005 c. 9.

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**Status:** *This is the original version (as it was originally made).*

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