

Draft Regulations laid before the National Assembly for Wales on 7 February 2011 under section 11(6) of the NHS Redress (Wales) Measure 2008, for approval by resolution of the National Assembly for Wales.

W E L S H S T A T U T O R Y
I N S T R U M E N T S

2011 No. (W.)

**NATIONAL HEALTH
SERVICE, WALES**

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the Regulations”) make new arrangements for the notification and consideration of and response to concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales.

A concern is defined as a complaint, a notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation.

The Regulations also introduce the concept of “redress”. They place an obligation on a Welsh NHS body to consider, when it is notified of a concern that alleges harm has or may have been caused, whether or not there is a qualifying liability.

Part 7 of the Regulations contains provisions detailing how the redress arrangements will operate when a Welsh NHS body enters into arrangements with an NHS body in England, Scotland or Northern Ireland.

The redress elements of the Regulations do not apply to primary care providers or independent providers.

The Regulations replace the existing arrangements for the making and consideration of complaints which are contained in three separate sets of Directions. The Regulations revoke the Directions, subject to transitional provisions, and make, in Schedule 2, consequential amendments to the relevant terms of service for primary care providers in Wales.

Part 1

General

The Regulations apply to services provided as part of the health service in Wales.

Parts 1 to 6 and 8 to 10 of the Regulations come into force on 1 April 2011. Part 7 of the Regulations comes into force on 1 October 2011.

Regulation 2 defines terms used in the Regulations. Key definitions include the definition of “complaint”, “concern”, “primary care provider”, “qualifying liability in tort”, “qualifying services” and “responsible body”.

Regulation 3 establishes the general principles which must be followed when handling and investigating concerns under the Regulations.

Part 2

Duty to Make Arrangements for the Handling and Investigation of Concerns

Regulation 4 provides that a responsible body must make arrangements, in accordance with these Regulations, for the handling and investigation of concerns.

Regulation 5 provides that arrangements for handling concerns must be published in accordance with the provisions of that regulation.

Regulation 6 stipulates that a responsible body is required to designate a person to be responsible for the oversight of its operation of the arrangements under the Regulations. Regulation 7 provides that a responsible officer must be designated to take responsibility for the day to day operation of the process to ensure concerns are dealt with in an integrated manner. Regulation 8 requires a responsible body to designate a senior investigations manager who will oversee the handling and consideration of concerns.

Regulation 9 provides that a responsible body must ensure that its staff receive appropriate training to enable them to comply with the requirements of the Regulations.

Part 3

Nature and Scope of the Arrangements for Handling Concerns

Regulation 10 provides that a responsible body must handle concerns in accordance with the arrangements for handling concerns set out in the Regulations. Regulation 10 is expressed to be subject to regulation 14 which sets out which matters and concerns are excluded from consideration under the Regulations.

Regulation 11 provides that a concern may be notified in writing, electronically or verbally. If a concern is notified verbally a written record of the concern must be prepared and a copy provided to the person who notified the concern.

Regulation 12(1) sets out who may notify a concern under the Regulations. Regulation 12(2) provides that a representative may notify a concern on behalf of a person who is receiving or has received services where that person has died, is a child, lacks capacity or has simply requested a representative to act on his or her behalf. Regulation 12(3) deals with the notification of concerns by a representative on behalf of a child. Pursuant to regulation 12(4) a responsible body must provide a child who notifies a concern with such assistance as the child may reasonably require to pursue the concern. Regulations 12(5) and (6) deal with the consideration of concerns notified on behalf of children and persons who lack capacity where the responsible body is of the opinion that the representative who notified the concern is not a suitable person to act as a representative or who is not pursuing the concern in the best interests of the child or person who lacks capacity. Regulation 12(7) deals with concerns that are reported by a member of staff of a responsible body and sets out when a patient must be informed of and involved in the investigation of such concerns. Regulation 12(8) sets out the circumstances in which a responsible body may form the opinion that a patient should not be informed of and involved in the investigation of such concerns.

Regulation 13 sets out the matters in respect of which concerns may be notified. A concern may be notified to: a Local Health Board or a National Health Service Trust managing a hospital or other establishment wholly or mainly in Wales about any matter connected with the exercise of its functions; to a primary care

provider (which is defined in regulation 2 to be limited to primary care providers in Wales providing services pursuant to the National Health Service (Wales) Act 2006) about the provision of services by it under a contract or arrangements with a Welsh NHS body; or an independent provider in Wales about the provision of services by it under arrangements with a Welsh NHS body. Provided the requirements of regulation 18 are met, a person may also notify a concern to a Local Health Board about any matter connected with the provision of services by a primary care provider under a contract or arrangement with the Local Health Board.

Regulation 14(1) sets out the matters and concerns which are excluded from the scope of the arrangements under the Regulations. Regulation 14(2) provides that a responsible body must, as soon as reasonably practicable, notify in writing the person who notified the concern if it is of the opinion that the matter or concern relates to an excluded matter or concern and provide the reason for its decision.

Regulation 15 sets out the time limits for the notification of concerns under the Regulations.

Regulation 16 provides that a concern may be withdrawn at any time by the person who notified the concern. The withdrawal may be notified in writing, electronically or verbally. Regulation 16(3) provides that even if a concern is withdrawn, a responsible body may continue to investigate any issues raised by a concern if it considers that it is necessary to do so.

Part 4

Concerns which involve other Responsible Bodies

Regulation 17 deals with concerns involving more than one responsible body. It places a duty on responsible bodies to co-operate for the purposes of co-ordinating the handling and investigation of the concern notified and must ensure that the person who notified the concern receives a co-ordinated response.

Regulations 18, 19, 20 and 21 deal with concerns about primary care providers which are notified to the Local Health Board with whom the primary care provider, who is the subject of the concern, has entered into a contract or arrangement. Regulation 19 deals with the action that a Local Health Board must take when it receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider. Regulation 20 deals with the action that a Local Health Board must take when it receives a concern notified by a primary care provider. Both regulations 19 and 20 require a Local Health

Board to consider whether or not it is appropriate for it to consider the concern or whether it is more appropriate for the primary care provider who is the subject of the concern to consider it. Regulation 21 deals with notification by a Local Health Board of the decision made under regulation 19 or 20. It sets out the relevant time limit for making a decision and the duty on the Local Health Board to give a reason for the decision.

Part 5

Handling and Investigation of Concerns

Regulation 22 provides that unless specified exceptions apply, a responsible body must notify receipt of a concern not later than two working days after receipt. A responsible body must also offer to discuss with the person who notified the concern matters relating to the investigation of the concern outlined in regulation 22(4). Pursuant to regulation 22(6) a responsible body must send a copy of the notification of a concern to the person who is the subject of the concern unless it is of the view that provision of a copy would, in its reasonable opinion, prejudice its consideration of the matters raised by the concern.

Regulation 23 provides that a responsible body must investigate the matters raised by a concern in the manner which appears to that body to be the most appropriate. It must have particular regard to the matters raised in regulation 23(1). Regulation 23(1)(i) provides that where a Welsh NHS body receives notification of a concern which includes an allegation that harm has or may have been caused it must consider the likelihood of any qualifying liability; the duty to consider redress in accordance with the provisions of regulation 25; and, where appropriate, consideration of the additional requirements set out in Part 6.

Regulation 24 sets out the requirements for a response to an investigation under regulation 23. Regulation 24 does **not** apply where a Welsh NHS body considers that there is or there may be a qualifying liability. In those circumstances an interim report under regulation 26 must be produced. In all other circumstances, a response under regulation 24 must be prepared. Regulation 24(1) prescribes the content of a response under regulation 24. Regulation 24(3), (4) and (5) prescribe the timescales for sending a response to the person who notified the concern. Regulation 24(3) places a duty on Welsh NHS bodies to provide reasons if, in relation to a concern that alleges harm has been or may have been caused, they come to the decision

that there is no qualifying liability and the redress arrangements in Part 6 will not be triggered.

Part 6

Redress

The duty to consider redress under Part 6 only applies to Welsh NHS bodies, which are defined in regulation 2 as Local Health Boards and National Health Service Trusts managing a hospital or other establishment or facility wholly or mainly in Wales. It does not apply to primary care providers or independent providers.

Regulation 25 provides that where a Welsh NHS body determines during the course of an investigation in accordance with regulation 23 that a qualifying liability exists or may exist, it must determine whether or not an offer of redress should be made to the patient. Regulation 25(2) makes it clear that an offer of redress may be made by a Welsh NHS body where it is established that there is a qualifying liability.

Regulation 26 states that where a Welsh NHS body is of the opinion, following an investigation under regulation 23, that there is or there may be a qualifying liability it must produce an interim report. Regulation 26(1) prescribes the content of the interim report. Regulation 26(2), (3) and (4) set out the timescales for sending the interim report to the person who notified the concern. Regulation 26(5) and (6) prescribe the timescale for sending the person who notified the concern, or his or her legal representative, a copy of the investigation report referred to in regulation 31.

Regulation 27 sets out the form that redress may take under the Regulations.

Regulation 28 provides that redress is not available in relation to a liability that is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress must stop and the person who notified the concern must be so advised.

Regulation 29 sets the limit for the financial compensation element of redress at £25,000. This is for special and general damages. Regulation 29(2) provides that if, on investigation, it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Regulations, must not be offered. However, regulation 29(3) provides that if the financial limit will be exceeded, a Welsh NHS body may give consideration to making an offer of settlement outside the provisions of these Regulations. The regulation provides that the value of any

compensation awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue a compensation tariff.

Regulation 30 deals with suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 6 of the Regulations.

Regulation 31 provides that the findings of an investigation of a concern must be recorded in an investigation report. Regulation 31(2) sets out what must be included in an investigation report. Regulation 31(3) provides that unless the provisions of regulation 31(4) apply, a Welsh NHS body must provide the person who is seeking redress under Part 6 of the Regulations, or his or her legal representative, with a copy of the investigation report.

Regulation 32 provides that where a Welsh NHS body has determined that a qualifying liability exists or may exist it must ensure that legal advice is available, in accordance with the provisions of this regulation. It must also ensure that if medical experts need to be instructed, they are instructed jointly by the Welsh NHS body and the person who notified the concern. Regulation 32(2) provides that legal advice can only be sought from firms of solicitors who have at least one partner or employee who is a member of either the Law Society Clinical Negligence Panel or the Action Against Medical Accidents Clinical Negligence Panel. Regulation 32(3) sets out the matters in respect of which legal advice, without charge to the person who notified the concern, must be made available. Regulation 32(4) provides that the cost of such legal advice and costs arising from the instruction of medical experts must be borne in their entirety by the Welsh NHS body.

Regulation 33 prescribes the time limits that apply to the making of offers of redress; the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 33(e) provides that any offer of settlement will be by way of 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. Regulation 33(g) provides that where a settlement is subject to court approval, the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

Part 7

Requirements 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.

Part 7 deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with NHS bodies in England, Scotland or Northern Ireland. Primary care providers and independent providers are excluded from the scope of the arrangements under Part 7.

Regulation 34 defines terms that are used in Part 7.

Regulation 35 places a duty on an “English NHS body”, which is a term defined in regulation 34, that receives notification of a concern or a complaint about a service which it has provided or arranged for the provision of under arrangements with a Welsh NHS body, to consider, when investigating the complaint or concern, whether or not a qualifying liability exists or may exist.

Regulation 36(1) provides that if an English NHS body concludes that such a liability exists or may exist it must take the steps outlined in regulation 36(2).

Regulation 36(2) places a duty on an English NHS body to notify the Welsh NHS body with whom it has entered into an arrangement if it is of the view that a qualifying liability exists or may exist. It must then, after obtaining the appropriate consents from the patient or, in certain cases his or her representative, provide the Welsh NHS body with the information and documentation outlined at paragraphs (a) to (f).

Regulation 37 prescribes the action that a Welsh NHS body must take when it receives notification from an English NHS body in accordance with regulation 36.

Regulation 38 prescribes the action that a Welsh NHS body is required to take if it receives a notification from a Scottish NHS body or a Northern Irish NHS body that there is, or there may be, a qualifying liability.

Regulation 39 places a duty on Welsh NHS bodies to conduct an investigation on receipt of a notification from an English NHS body, a Scottish NHS body or a Northern Irish NHS body. Regulation 39(2) places a duty of co-operation on Welsh NHS bodies and English NHS bodies.

Regulation 40 provides that if after conducting an investigation in accordance with regulation 39 a Welsh NHS body is of the opinion that there is or there may be a qualifying liability, the Welsh NHS body must produce an interim report. Regulation 40(1) prescribes the content of the report. Regulation 40(3) and (4)

prescribe the timescales for sending the interim report to the person who notified the concern. Regulation 40(4) prescribes the timescale for sending the person who notified the concern a copy of the investigation report referred to in regulation 46.

Regulation 41 prescribes the action that a Welsh NHS body must take when, following an investigation in accordance with the provisions of regulation 39, it decides that a concern notified by an English NHS body in accordance with regulation 36 or a Scottish NHS body or Northern Irish NHS body (in accordance with provisions in a commissioning contract) does not involve a qualifying liability.

Regulation 42 sets out the form that redress may take under Part 7 of the Regulations.

Regulation 43 provides that redress is not available in relation to a liability that is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress must stop and the Welsh NHS body must notify the person who notified the concern and the English NHS body, Scottish NHS body or Northern Irish NHS body as appropriate.

Regulation 44 sets the limit for the financial element of redress at £25,000. This is for special and general damages. Regulation 44(2) provides that if, on investigation, it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Regulations, must not be offered. The regulation provides that the compensation awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue, a compensation tariff.

Regulation 45 deals with the suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 7 of the Regulations.

Regulation 46 provides that the findings of an investigation of a concern must be recorded in an investigation report. Regulation 46(2) sets out what must be included in an investigation report. Regulation 46(3) provides that unless the provisions of regulation 46(4) apply, a Welsh NHS body must provide the person who is seeking redress under Part 7 of the Regulations, or his or her legal representative, with a copy of the investigation report.

Regulation 47 replicates the provisions in regulation 32 save that regulation 47(4) makes reference to the fact that a Welsh NHS body may have rights to

recover the cost of any expenditure related to redress from an English NHS body.

Regulation 48 prescribes the time limits that apply to the making of offers of redress; the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 48(e) provides that any offer of settlement will be by way of 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. Regulation 48(g) provides that where a settlement is subject to court approval the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

Part 8

Learning from concerns

Regulation 49 provides that each responsible body must ensure that it has processes in place to ensure that any deficiencies in its actions or service provision that are identified as part of an investigation of a concern in accordance with these Regulations are acted upon and monitored.

Part 9

Monitoring the Process

Regulation 50 prescribes the matters a responsible body must keep a record of in order to monitor the operation of the arrangements for dealing with concerns under the Regulations.

Regulation 51 provides that a responsible body must prepare an annual report. Regulation 51(1) prescribes the content of the annual report. Regulation 51(2) and (3) together provide that an independent provider, a primary care provider or a NHS Trust managing a hospital or other establishment wholly or mainly in Wales must if it agrees to provide services under an arrangement with a Local Health Board, send a copy of its annual report to that Local Health Board.

Part 10

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Regulation 52 contains transitional provisions.

Regulation 53 revokes the Directions specified in paragraphs (a) to (c).

Regulation 54 gives effect to Schedule 2.

Draft Regulations laid before the National Assembly for Wales on 7 February 2011 under section 11(6) of the NHS Redress (Wales) Measure 2008, for approval by resolution of the National Assembly for Wales.

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I N S T R U M E N T S

2011 No. (W.)

**NATIONAL HEALTH
SERVICE, WALES**

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

Made

*Coming into force in accordance with the
provisions of regulation 1(2)*

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PART 1

GENERAL

The Welsh Ministers, in exercise of the powers conferred by the provisions set out in column (1) of Schedule 1 to this instrument, as amended in particular by the provisions set out in column (2) of that Schedule, make the following Regulations.

A draft of these Regulations was laid before, and approved by resolution of, the National Assembly for Wales in accordance with section 11(6) of the NHS Redress (Wales) Measure 2008.

Title, commencement and application

1.—(1) The title of these Regulations is the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

(2) Parts 1 to 6 and 8 to 10 come into force on 1 April 2011 and Part 7 comes into force on 1 October 2011.

(3) These Regulations apply to services provided as part of the health service in Wales.

Interpretation

2.—(1) In these Regulations—

“the 2006 Act” (“*Deddf 2006*”) means the National Health Service (Wales) Act 2006⁽¹⁾;

“alternative dispute resolution” (“*dull amgen o ddatrys anghydfod*”) means mediation, conciliation or facilitation;

“child” (“*plentyn*”) means a person who has not attained the age of eighteen years;

“complaint” (“*cwyn*”) means any expression of dissatisfaction;

“concern” (“*pryder*”) means any complaint; notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation;

“disciplinary proceedings” (“*achos disgyblu*”) means any procedure for disciplining employees adopted by a responsible body for disciplining employees;

(1) 2006 c.42.

“executive director” (“*cyfarwyddwr gweithredol*”) means a member of the Board of a National Health Service Trust who is an employee of that body;

“general dental services contractor” (“*contractwr gwasanaethau deintyddol cyffredinol*”) means a person who has entered into a contract to provide general dental services with a Local Health Board in accordance with section 57 of the 2006 Act;

“general medical services contractor” (“*contractwr gwasanaethau meddygol cyffredinol*”) means a person who has entered into a contract to provide general medical services with a Local Health Board in accordance with section 42 of the 2006 Act;

“health care professional” (“*proffesiynolyn gofal iechyd*”) means a member of a profession (whether or not regulated by, or by virtue of, any enactment) which is concerned (wholly or partly) with the physical or mental health of individuals;

“incident concerning patient safety” (“*digwyddiad sy’n ymwneud â diogelwch claf*”) means any unexpected or unintended incident which did lead to or could have led to harm for a patient;

“independent provider” (“*darparwr annibynnol*”) means a person or body who—

- (a) provides health care in Wales under arrangements made with a Welsh NHS body; and
- (b) is not an NHS body or a primary care provider;

“individual patient treatment request” (“*cais am driniaeth i glaf unigol*”) means a request to a Local Health Board to fund health care for an individual patient that falls outside the range of services and treatments that the Local Health Board provides including those specialist services secured through the Welsh Health Specialist Services Committee.

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a Local Health Board established in accordance with section 11(2) of the 2006 Act;

“moderate or severe harm” (“*niwed cymedrol neu ddifrifol*”) means moderate or severe harm determined in accordance with guidance issued for the purpose of these Regulations by the Welsh Ministers;

“non-executive director” (“*cyfarwyddwr anweithredol*”) means a member of the Board of a National Health Service Trust who is not an employee of that body;

“non-officer member” (“*aelod nad yw’n swyddog*”) means a member of the Board of a Local Health Board who is not an employee of that body;

“officer member” (“*aelod sy’n swyddog*”) means a member of the Board of a Local Health Board who is an employee of that body;

“patient” (“*claf*”) means the person who receives or has received services from a responsible body;

“primary care provider” (“*darparwr gofal sylfaenol*”) means a person or body who—

- (a) is a general medical services contractor;
- (b) provides primary medical services in accordance with arrangements made under sections 41(2)(b) and 50 of the 2006 Act;
- (c) is a general dental services contractor;
- (d) provides primary dental services in accordance with arrangements under section 64 of the 2006 Act;
- (e) provides general ophthalmic services in accordance with arrangements under section 71 of the 2006 Act;
- (f) provides pharmaceutical services in accordance with arrangements under section 80 of the 2006 Act;
- (g) provides local pharmaceutical services under pilot schemes pursuant to section 92 of the 2006 Act; or
- (h) provides local pharmaceutical services pursuant to paragraph 1 of Schedule 7 to the 2006 Act;

“qualifying liability” (“*atebolrwydd cymwys*”) means a liability in tort owed in respect of, or consequent upon, personal injury or loss arising out of or in connection with breach of a duty of care owed to any person in connection with the diagnosis of illness, or in the care or treatment of any patient—

- (a) in consequence of any act or omission by a health care professional; and
- (b) which arises in connection with the provision of qualifying services;

“relevant complaints procedure” (“*gweithdrefn gwynion berthnasol*”) means—

- (a) any arrangements for the handling and consideration of complaints that are required or have been required to be established and operated respectively by any of the following directions—
 - (i) Directions to NHS Trusts and Local Health Boards on Hospital Complaints Procedures signed on 27 March 2003;

(ii) Directions to Local Health Boards on Dealing with Complaints about Family Health Services Practitioners, Providers of Personal Medical Services and Providers of Personal Dental Services other than Personal Dental Services Provided by NHS Trusts signed on 27 March 2003;

(iii) Miscellaneous Directions to Local Health Boards for Dealing with Complaints signed on 27 March 2003⁽¹⁾;

(b) any arrangements for the handling and consideration of complaints that may at any time be or have been required by paragraph 28 of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992⁽²⁾;

(c) any arrangements for the handling and consideration of complaints that may at any time be or have been required to be established and operated respectively by any of the following provisions—

(i) paragraph 39 of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992;

(ii) paragraph 22 of Schedule 2A to the National Health Service (Pharmaceutical Services) Regulations 1992;

(iii) paragraph 90 of Schedule 6 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004⁽³⁾;

(iv) paragraph 8A of Schedule 1 to the National Health Service (General Ophthalmic Services) Regulations 1986⁽⁴⁾;

(v) paragraph 47 of Schedule 3 to the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006⁽⁵⁾;

(vi) paragraph 47 of Schedule 3 to the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006⁽⁶⁾;

“responsible body” (*“corff cyfrifol”*) means—

(a) a Welsh NHS body;

(b) a primary care provider; or

(1) Copies of the Directions referred to in the definition of “relevant complaints procedure” may be obtained from the library at the Welsh Assembly Government, Cathays Park, Cardiff, CF10 3NQ.

(2) S.I. 1992/662.

(3) S.I. 2004/478 (W.48).

(4) S.I. 1986/975.

(5) S.I. 2006/490 (W.59).

(6) S.I. 2006/489 (W.58).

(c) an independent provider;

“staff” (“*staff*”) means any person who is employed by or engaged to provide health care services for a responsible body;

“Welsh NHS body” (“*corff GIG Cymru*”) means—

(a) a Local Health Board; or

(b) a National Health Service Trust managing a hospital or other establishment or facility wholly or mainly in Wales;

“working day” (“*diwrnod gwaith*”) means a day except Saturday or Sunday, Christmas Day, Boxing Day, Good Friday, or a day which is a bank holiday in Wales under the Banking and Financial Dealings Act 1971(1).

(2) For the purposes of Part 7, “qualifying services” (“*gwasanaethau cymwys*”) means services provided in the United Kingdom as part of the health service in Wales (this does not include services provided in Wales commissioned as part of the health service in England, Scotland or Northern Ireland).

(3) For the purposes of regulation 3 and Parts 5 and 6, “qualifying services” (“*gwasanaethau cymwys*”) means services provided in Wales as part of the health service in Wales (this does not include services provided in Wales commissioned as part of the health service in England, Scotland or Northern Ireland).

General principles for the handling and investigation of concerns

3. Any arrangements set up under these Regulations for the handling and investigation of concerns must be such as to ensure that—

- (a) there is a single point of entry for the submission of concerns;
- (b) concerns are dealt with efficiently and openly;
- (c) concerns are properly investigated;
- (d) provision should be made to establish the expectations of the person notifying the concern and to seek to secure their involvement in the process;
- (e) persons who notify concerns are treated with respect and courtesy;
- (f) persons who notify concerns are advised of—

(1) 1971 c.80.

- (i) the availability of assistance to enable them to pursue their concern;
- (ii) advice as to where they may obtain such assistance, if it is required; and
- (iii) the name of the person in the relevant responsible body who will act as their contact throughout the handling of their concern;
- (g) a Welsh NHS body must give consideration to the making of an offer of redress in accordance with Part 6 where its investigation into the matters raised in a concern reveal that there is a qualifying liability;
- (h) persons who notify concerns receive a timely and appropriate response;
- (i) persons who notify concerns are advised of the outcome of the investigation;
- (j) appropriate action is taken in the light of the outcome of the investigation; and
- (k) account is taken of any guidance that may be issued from time to time by the Welsh Ministers.

PART 2

DUTY TO MAKE ARRANGEMENTS FOR THE HANDLING AND INVESTIGATION OF CONCERNS

Duty to make arrangements

4. A responsible body must make arrangements in accordance with these Regulations for the handling and investigation of concerns (“arrangements for dealing with concerns”).

Arrangements to be published

5. The arrangements for dealing with concerns must be published in a variety of media, formats and languages and a copy of the arrangements must be given free of charge to any person who requests it, in the format that has been requested.

Strategic oversight of the arrangements

6.—(1) Each responsible body must designate a person to be responsible for maintaining a strategic overview of its operation of the arrangements under these Regulations, in particular to—

- (a) ensure that the responsible body complies with its arrangements for dealing with concerns; and
- (b) undertake the functions set out in Part 8.

(2) Where the responsible body is a Welsh NHS body, this person must be one of its non-officer members or non-executive directors, as appropriate.

Responsible officer

7.—(1) Each responsible body must designate a person in these Regulations referred to as the responsible officer, to take overall responsibility for the effective day to day operation of the arrangements for dealing with concerns in an integrated manner.

(2) For the purposes of this regulation “integrated manner” means that the process for dealing with concerns, and, if there is a duty under the Regulations to consider qualifying liabilities, claims management reporting are dealt with under a single governance arrangement.

(3) The responsible officer is to be—

- (a) in the case of a Welsh NHS body, a person who is an officer member or executive director of that body, as appropriate;
- (b) in the case of any other responsible body, the person who acts as the chief executive officer of that body or, if there is none—
 - (i) the person who is the sole proprietor of the responsible body;
 - (ii) where the responsible body is a partnership, a partner; or
 - (iii) in any other case, a director of the responsible body, or a person who is responsible for managing the responsible body.

(4) The functions of the responsible officer may be performed by that person or by any person authorised by the responsible body to act on his or her behalf provided that the person so authorised is under the direct control and supervision of the responsible officer.

Senior investigations manager

8.—(1) Each responsible body must designate at least one person, in these Regulations referred to as a senior investigations manager, to undertake responsibility for the handling and consideration of concerns notified in accordance with the arrangements for handling concerns and in particular to—

- (a) perform the functions of a senior investigations manager under the arrangements for dealing with concerns;

- (b) perform such other functions relating to the handling and consideration of concerns as the responsible body may require; and
- (c) co-operate with such other persons or bodies as may be necessary to facilitate the handling and consideration of concerns.

(2) The responsible body must ensure that the senior investigations manager appointed by that body has a sufficient number of staff of the required level of seniority to assist in the carrying out of his or her functions and that such members of staff receive adequate training to enable them to fulfil their responsibilities under the arrangements for dealing with concerns.

(3) The functions of a senior investigations manager under paragraph (1) may be performed personally or by a person or persons authorised by the responsible body to act on behalf of the senior investigations manager.

(4) The functions of a senior investigations manager may be carried out by the senior investigations manager designated by another responsible body under paragraph (1).

Information and training for staff

9. Each responsible body must ensure that its staff are informed about and receive appropriate training in respect of the operation of the arrangements for the reporting, handling and investigation of concerns.

PART 3

NATURE AND SCOPE OF THE ARRANGEMENTS FOR HANDLING CONCERNS

Requirement to consider concerns

10. Subject to regulation 14, a responsible body must handle a concern in accordance with the arrangements for handling concerns set out in these Regulations if it is notified on or after the 1 April 2011—

- (a) in accordance with regulation 11;
- (b) by a person specified in accordance with regulation 12;
- (c) about a matter specified in regulation 13; and
- (d) within the period specified in regulation 15.

Notification of concerns

11.—(1) A concern may be notified—

- (a) in writing;

- (b) electronically; or
- (c) verbally, either by telephone or in person, to any member of the staff of the responsible body, the exercise of whose functions is the subject of the concern.

(2) Subject to regulation 14(1)(f), where a concern is notified verbally, the member of staff of the responsible body to whom the concern has been notified must—

- (a) make a written record of the concern; and
- (b) provide a copy of the written record to the person who notified the concern.

Persons who may notify concerns

12.—(1) A concern may be notified by—

- (a) a person who is receiving or has received services from a responsible body in relation to the services being received or having been received;
- (b) any person who is affected, or likely to be affected by the action, omission or decision of a responsible body the exercise of whose functions is the subject of the concern;
- (c) a non-officer member or a non-executive director of a responsible body;
- (d) a member of the staff of a responsible body; or
- (e) a partner in a responsible body.

(2) A concern may be notified by a person (in this regulation referred to as a representative) acting on behalf of a person mentioned in paragraph (1) who—

- (a) has died;
- (b) is a child;
- (c) is unable to notify the concern themselves because they lack capacity within the meaning of the Mental Capacity Act 2005(1); or
- (d) has requested the representative to act on their behalf.

(3) Where a representative notifies a concern on behalf of a child, the responsible body to which the concern has been notified—

- (a) must not consider the concern unless it is satisfied that there are reasonable grounds for the concern being notified by a representative instead of the child; and

(1) 2005 c.9.

- (b) if it is not so satisfied, must notify the representative in writing and state the reason for its decision.

(4) Where a concern is notified by a child, the responsible body must provide the child with such assistance as the child may reasonably require in order to pursue the concern.

(5) This paragraph applies where—

- (a) a representative notifies a concern on behalf of—
 - (i) a child; or
 - (ii) a person who lacks capacity within the meaning of the Mental Capacity Act 2005; and
- (b) the responsible body to which the concern has been notified is satisfied that there are reasonable grounds to conclude that the representative is not a suitable person to act as representative or is not pursuing the concern in the best interests of the person on whose behalf the concern has been notified.

(6) Where paragraph (5) applies—

- (a) save where sub-paragraph (6)(b) also applies, the concern may not be considered or further considered in accordance with arrangements made under these Regulations and the responsible body must notify the representative in writing and state the reason for the decision;
- (b) if the responsible body is satisfied that it is necessary to do so, it may continue to investigate any issue raised by the concern notified in accordance with paragraph (5), but in these circumstances it is under no obligation to provide a response in accordance with regulation 24, unless it considers that it is reasonable to do so.

(7) Unless paragraph (8) applies, where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern and involve the patient, or his or her representative, in the investigation of the concern in accordance with Part 5.

(8) Where, in the opinion of the responsible body, it would not be in the interests of the patient to be informed of or involved in the investigation of the concern it must—

- (a) make a written record of this decision and the reasons for it; and

- (b) keep the decision under review during the investigation of concern.

(9) In these Regulations any reference to a person who notifies a concern or is seeking redress includes a reference to a representative of that person.

Matters about which concerns may be notified

13. A concern may be notified in accordance with these Regulations to—

- (a) a Welsh NHS body about any matter connected with the exercise of its functions;
- (b) a primary care provider about the provision of services by it under a contract or arrangements with a Welsh NHS body;
- (c) an independent provider about the provision of services by it under arrangements with a Welsh NHS body; or
- (d) provided that the requirements set out in regulation 18 are met, a Local Health Board about any matter connected with the provision of services by a primary care provider under a contract or arrangements with the Local Health Board.

Matters and concerns excluded from consideration under the arrangements

14.—(1) The following are matters and concerns which are excluded from the scope of the arrangements required under these Regulations—

- (a) a concern notified by a primary care provider which relates to the contract or arrangements under which it provides primary care services;
- (b) a concern notified by a member of staff of a responsible body about any matter relating to that person's contract of employment;
- (c) a concern which is being or has been investigated by the Public Services Ombudsman for Wales⁽¹⁾;
- (d) a concern arising out of an alleged failure by a responsible body to comply with a request for information under the Freedom of Information Act 2000⁽²⁾;
- (e) disciplinary proceedings which a responsible body is taking, or is proposing to take, as a result of, or arising from the investigation of, a concern notified in accordance with

⁽¹⁾ A concern which is being or has been investigated in accordance with the relevant provisions of the Public Services Ombudsman (Wales) Act 2005. 2005 c.10.

⁽²⁾ 2000 c.36.

arrangements for dealing with concerns made under these Regulations;

- (f) a concern which is notified verbally, either in person, or on the telephone and is resolved to the satisfaction of the person who notified the concern not later than the next working day after the day on which the concern was notified;
- (g) a concern, the subject matter of which is the same as that of a concern that has previously been notified and resolved in accordance with sub-paragraph (f) unless the responsible body considers that it is reasonable to re-open the consideration of the concern and to undertake an investigation in accordance with Part 5;
- (h) a concern, the subject matter of which has previously been considered in accordance with arrangements made under—
 - (i) these Regulations; or
 - (ii) any relevant complaints procedure in relation to a complaint which was made before 1 April 2011;
- (i) a concern, the subject matter of which is, or becomes, the subject of civil proceedings; or
- (j) a concern the subject matter of which is, or becomes, a concern related to an individual patient treatment request.

(2) Subject to paragraph (3), where a concern or matter is a concern or matter specified in paragraph (1), and a responsible body makes a decision to that effect, the responsible body must as soon as reasonably practicable notify in writing the person who notified the concern or matter of its decision and the reason for its decision.

(3) Paragraph (2) does not apply to a matter specified in sub-paragraph (f) of paragraph (1).

(4) Where a matter specified in paragraph (1) is part of, or is connected with, another matter which is not so specified, nothing in this regulation prevents that other matter being considered as a concern notified in accordance with arrangements made under these Regulations.

Time limit for notification of concerns

15.—(1) Subject to paragraph (2), a concern must be notified not later than twelve months after—

- (a) the date on which the matter which is the subject of the concern occurred; or
- (b) if later, the date on which the matter which is the subject of the concern came to the notice of the person notifying the concern.

(2) Subject to paragraph (3), the time limit in paragraph (1) will not apply if the responsible body is satisfied that—

- (a) the person notifying the concern had good reasons for not notifying the concern within that time limit; and
- (b) notwithstanding the delay, it is still possible to investigate the concern effectively and fairly.

(3) A concern may not be notified three or more years after the date on which the matter which is the subject of the concern occurred or, if later, three or more years from the date on which the matter which is the subject of the concern came to the notice of the patient.

(4) In respect of paragraphs (1) and (2), a reference to the date on which the matter which is the subject of the concern came to the notice of the person notifying the concern is, where a patient has opted to have a representative act on his or her behalf in accordance with regulation 12(2)(d), a reference to the patient's date of knowledge and not to that of the representative who is notifying the concern on the patient's behalf.

Withdrawal of concerns

16.—(1) A concern may be withdrawn at any time by the person who notified the concern and the withdrawal may be notified—

- (a) in writing;
- (b) electronically; or
- (c) verbally, either by telephone or in person.

(2) The responsible body must as soon as practicable write to the person who has withdrawn a concern verbally to confirm the verbal withdrawal of a concern.

(3) Where a concern has been withdrawn, a responsible body may nevertheless continue to investigate any issues raised by a concern in accordance with Part 5, should the responsible body consider that it is necessary to do so.

PART 4

CONCERNS WHICH INVOLVE OTHER RESPONSIBLE BODIES

Concerns involving more than one responsible body

17.—(1) This regulation applies in any case where—

- (a) the person who notifies a concern has raised issues which involve the exercise of

functions by more than one responsible body; or

- (b) it appears to a responsible body (“the first body”) that a concern which has been notified to it is or may be a concern which relates to the exercise of functions of another responsible body (“the second body”).

(2) Where paragraph (1)(b) applies the first body must, if the concern has been notified by a patient or, in accordance with regulation 12, his or her representative—

- (a) within two working days of receipt of the notification of the concern, seek the consent of the person who notified the concern to the notification of the second body or bodies involved; and
- (b) notify the second body or bodies involved within two working days of receipt of the consent mentioned in sub-paragraph (a).

(3) The first body and the second body or bodies must co-operate for the purposes of—

- (a) co-ordinating the handling and consideration of the concern; and
- (b) ensuring that the person who notified the concern receives a co-ordinated response to the concern or concerns that he or she has notified.

(4) The duty to co-operate under paragraph (3) includes, in particular, a duty for each body—

- (a) to seek to agree which of the bodies involved should take the lead in—
 - (i) co-ordinating the handling and consideration of the concern; and
 - (ii) communicating with the person who notified the concern;
- (b) subject to obtaining the appropriate consents, to provide to the other body or bodies information relevant to the handling and consideration of the concern which is reasonably requested by another body; and
- (c) to ensure that it is represented at any meeting reasonably required in connection with the handling and consideration of the concern.

Concerns involving primary care providers

18. This regulation and regulations 19, 20 and 21 apply to a concern—

- (a) notified to a Local Health Board on or after 1 April 2011 in accordance with arrangements for dealing with concerns made under these Regulations;

- (b) about the services provided by a primary care provider under a contract or arrangements with a Local Health Board; and
- (c) which is not excluded from consideration in accordance with regulation 14.

Action to be taken where a Local Health Board receives notification of a concern about services provided by a primary care provider

19.—(1) When a Local Health Board receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider it must determine whether, in its opinion, the concern is appropriate for it to consider or whether it is more appropriate for the primary care provider that is the subject of the concern to consider.

(2) Before making a decision the Local Health Board must determine from the person who notified the concern, whether—

- (a) the concern has been considered by the primary care provider, and if so, whether a response has been issued by the provider in accordance with regulation 24; and
- (b) the person who notified the concern consents to details of the concern being sent to the primary care provider who is the subject of the concern.

(3) If a response has been issued by the primary care provider in accordance with regulation 24, the Local Health Board must not consider the concern.

(4) If the person notifying the concern does not consent to the Local Health Board sending details of the concern to the primary care provider, the Local Health Board must not investigate the concern unless notifying the primary care provider of the concern would, in the reasonable opinion of the Local Health Board, prejudice its consideration of the concern.

Action to be taken where a Local Health Board receives notification of a concern from a primary care provider

20.—(1) When a Local Health Board is notified of a concern by a primary care provider it must determine whether, in its opinion, the concern is appropriate for it to consider or whether it is more appropriate for the primary care provider who is the subject of the concern to consider.

(2) Before making the decision the Local Health Board must—

- (a) determine whether or not the concern has been considered by the primary care provider

and, if so, whether a response has been issued by the provider in accordance with regulation 24; and

- (b) determine whether or not the person who notified the concern consents to the Local Health Board considering the concern if it decides in accordance with paragraph (2) that it is appropriate for it to do so.

(3) If a response has been issued by the provider in accordance with regulation 24, the Local Health Board must not consider the concern.

(4) If the person who notified the concern is unwilling to consent to the Local Health Board dealing with the concern, the Local Health Board must not consider the concern.

Communication of decisions made by a Local Health Board in accordance with regulations 19 and 20

21.—(1) If the Local Health Board decides, in accordance with regulation 19(1) or 20(1) that it is appropriate for it to deal with a concern it must—

- (a) advise the person who notified the concern and the primary care provider of its decision; and
- (b) continue to deal with the concern in accordance with these Regulations.

(2) If the Local Health Board decides, in accordance with regulation 19(1) or 20(1) that it is more appropriate for the concern to be dealt with by the primary care provider the Local Health Board must advise the person who notified the concern and the primary care provider of its decision.

(3) When the primary care provider receives the notification of the decision issued by the Local Health Board under paragraph (2)—

- (a) the primary care provider must deal with the concern in accordance with these Regulations; and
- (b) the person who notified the concern is deemed to have notified the concern to the primary care provider in accordance with these Regulations.

(4) The time limit for notifying a decision made under regulation 19(1) or 20(1) is five working days from the date that the Local Health Board determines the matters outlined in regulation 19(2) or 20(2).

(5) A Local Health Board must give reasons for its decision under regulation 19(1) or 20(1).

(6) When a Local Health Board receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider and

the Local Health Board's decision is that it is more appropriate for the concern to be dealt with by the primary care provider who is the subject of the concern, the Local Health Board must advise the person who notified the concern of their right to notify a concern about the decision of the Local Health Board to the Public Services Ombudsman for Wales.

(7) The Local Health Board must not advise the primary care provider that it is investigating a concern in accordance with these Regulations where regulation 19(4) applies.

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.

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).

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.

PART 6

REDRESS

Duty to consider redress

25.—(1) Where an investigation of a concern is being undertaken in accordance with regulation 23 by a responsible body that is a Welsh NHS body and the Welsh NHS body determines that a qualifying liability exists or may exist, it must, in accordance with the provisions of this Part, determine whether or not an offer of redress should be made to the patient.

(2) An offer of redress may be made by a Welsh NHS body where it is established, in accordance with the provisions of these Regulations, that a qualifying liability exists.

Response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability

26.—(1) Where following an investigation under regulation 23 a responsible body that is a Welsh NHS body is of the opinion that there is or there may be a qualifying liability, that Welsh NHS body 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 23;
- (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 32;

- (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 31 will be made available, in accordance with the provisions of that regulation, to the person who is seeking redress;
- (i) contains details of the right to notify the concern 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 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 thirty 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 31 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.

Form of redress

27.—(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 27(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

28.—(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 these Regulations must cease and the Welsh NHS body must advise the person who notified the concern accordingly.

Redress – financial compensation

29.—(1) A Welsh NHS body may make an offer of redress for a qualifying liability by way of financial compensation in which the sum does not exceed £25,000.

(2) Where a Welsh NHS body considers that the value to be attributed to the qualifying liability exceeds £25,000, redress in the form of financial compensation must not be offered in accordance with this Part.

(3) If, in accordance with paragraph (2), a Welsh NHS body considers that the financial limit set by these Regulations will be exceeded, if the investigation conducted by the Welsh NHS body concludes that there is a qualifying liability, the Welsh NHS body may give consideration to making an offer of settlement outside the provisions of these Regulations.

(4) 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.

(5) If a tariff is issued in accordance with paragraph (4), 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

30.—(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⁽¹⁾ 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) for the period beginning with the date on which the initial concern which became an application for redress was received by a Welsh NHS body; and
- (b) subject to paragraphs (3), (4) and (5), up to and including the date when an offer of financial compensation made in accordance with regulation 33 is accepted by a patient or his or her representative by signing a formal agreement and legal waiver in accordance with regulation 33(e) or until such time as an offer of such compensation is rejected by a patient or his or her representative.

(3) A liability will no longer be considered as being the 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 33(f), limitation, if limitation is an issue, is suspended until the date upon which the court approves the settlement.

(5) In cases where a Welsh NHS body indicates, in accordance with regulation 33, that it is of the opinion 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 33.

Investigation report

31.—(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.

⁽¹⁾ 1980 c.58.

(2) An investigation report must contain the following—

- (a) a copy of any medical evidence that has been commissioned in accordance with this Part in order to determine whether or not 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 26(5) and (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

32.—(1) Where a Welsh NHS body has determined that a qualifying liability exists, or may exist, in accordance with regulation 26 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 has notified the concern in accordance with regulation 11.

(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 (1) or the Action Against Medical Accidents Clinical Negligence Panel (2).

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

- (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) 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

33. 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

(1) 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..

(2) 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..

make an offer of settlement within six months of the date that it is notified;

- (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 of the date of the offer or decision not to make an offer, the Welsh NHS body must be advised by the person who notified the concern or his or her legal representative 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 or decision as that is the time when, in accordance with regulation 30(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(1); 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.

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

(1) 2005 c.9.

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⁽¹⁾;
- (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⁽²⁾;
- (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—

- (a) a Health and Social Services Trust established under the Health and Personal Social Services (Northern Ireland) Order 1991⁽³⁾;

⁽¹⁾ 2006 c.41.

⁽²⁾ 1978 c.29.

⁽³⁾ S.I. 1991/194 (N.I.1).

- (b) the Regional Health and Social Care Board established under the Health and Social Care (Reform) Act 2009⁽¹⁾;
- (c) the Northern Ireland Blood Transfusion Service established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990⁽²⁾;
- (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

(1) 2009 c.1.

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

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.

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⁽¹⁾ 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.

⁽¹⁾ 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 (1) or the Action Against Medical Accidents Clinical Negligence Panel (2).

(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.

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- (1) 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..
 - (2) 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..

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⁽¹⁾; 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.

PART 8

LEARNING FROM CONCERNS

Learning from concerns

49.—(1) Each responsible body must ensure that it has in place arrangements to review the outcome of any concern that has been subject to an investigation under these Regulations in order to ensure that any deficiencies in its actions or its provision of services which are identified during the investigation are—

- (a) acted upon; and
- (b) monitored,

in order to ensure that any lessons learned are identified and promulgated throughout that body in order to improve the services that it provides and to seek to avoid such deficiencies recurring.

(2) The operation of the arrangements required by this Part is the responsibility of the person designated in accordance with regulation 6.

PART 9

MONITORING THE PROCESS

Monitoring the operation of arrangements for dealing with concerns

50. For the purposes of monitoring the operation of the arrangements for dealing with concerns under these Regulations each responsible body must maintain a record of the following matters—

- (a) each concern notified to it, including in the case of Welsh NHS bodies, any concerns notified in accordance with the provisions of Part 7;
- (b) the outcome of each concern; and
- (c) where the responsible body informed the person who notified the concern of—

(1) 2005 c.9.

- (i) the likely period within which a response would be issued in accordance with regulation 22(4)(c); or
- (ii) any extension to that period,
whether a response detailing the outcome of the investigation of the concern was sent to the person who notified the concern within that period, or any extended period.

Annual report

51.—(1) Each responsible body must prepare an annual report for each year which must—

- (a) specify the number of concerns which were notified to the responsible body, including, in the case of Welsh NHS bodies, any concerns that were notified to it in accordance with the provisions of Part 7;
- (b) specify the number of concerns which the responsible body determined to be well-founded;
- (c) specify the number of concerns that the responsible body has been advised have been notified to the Public Services Ombudsman for Wales;
- (d) summarise—
 - (i) the subject matter of concerns which were notified to the responsible body;
 - (ii) any matters of general importance arising out of those concerns, or the way in which they were handled;
 - (iii) any matters where action has been taken or is to be taken to improve services as a consequence of those concerns.

(2) This paragraph applies to a responsible body which is—

- (a) a Welsh NHS body other than a Local Health Board; or
- (b) a primary care provider or an independent provider,

and which in any year provides, or agrees to provide, services under arrangements with a Local Health Board.

(3) A responsible body to which paragraph (2) applies must send a copy of its annual report to the Local Health Board which arranged for the provision of the services by the responsible body.

PART 10
TRANSITIONAL AND CONSEQUENTIAL
PROVISIONS AND REVOCATIONS

Transitional provisions

52.—(1) In this regulation “the former complaints provisions” means any of the directions in relation to complaints which are revoked by regulation 53.

(2) Where before 1 April 2011—

- (a) a complaint has been made in accordance with any of the former complaints provisions; and
- (b) it is not excluded from consideration by any provision within the former complaints provisions,

it may be investigated, or continue to be investigated, as appropriate, in accordance with those provisions.

(3) Where in accordance with any of the former complaints provisions—

- (a) an investigation of a complaint has been conducted and completed by a complaints manager or an independent complaints facilitator; and
- (b) the person who made the complaint has made a request for a review by an independent review panel, the request must be dealt with in accordance with the former complaints provisions.

(4) Save in respect of a complaint which would be subject to the arrangements in Part 7 of these Regulations, where a complaint, the subject matter of which occurred before 1 April 2011—

- (a) has not been made in accordance with any of the former complaints provisions; and
- (b) it is not excluded from consideration by any provision within these Regulations,

it may be notified, considered and investigated in accordance with these Regulations.

(5) Complaints about services provided by English NHS bodies, Scottish NHS bodies or Northern Irish NHS bodies, as defined in regulation 34, made before 1 October 2011 will not be considered under Part 7 of these Regulations.

Revocations

53. Subject to regulation 52, the following directions made under the provisions listed in regulation 52(1)(a) are revoked:

- (a) the Directions to NHS Trust and Local Health Boards on Hospital Complaints Procedures, made on 27 March 2003;

- (b) the Directions to Local Health Boards on Dealing with Complaints about Family Health Services Practitioners, Providers of Personal Medical Services and Providers of Personal Dental Services, other than Personal Dental Services Provided by NHS Trusts, made on 27 March 2003; and
- (c) Miscellaneous Directions to Local Health Boards for Dealing with Complaints, made on 27 March 2003.

Consequential and transitional provisions

54. Schedule 2 (Consequential and Transitional Provisions) has effect.

Name

Minister for Health and Social Services, one of the Welsh Ministers

Date

SCHEDULE 1 Preamble

PROVISIONS CONFERRING POWERS
EXERCISED IN MAKING THESE
REGULATIONS

(1)	(2)
<i>Provision</i>	<i>Relevant amendments</i>
Health and Social Care (Community Health and Standards) Act 2003(1)	
Section 113(2)	Paragraph (d) was inserted by the NHS Redress (Wales) Measure 2008, section 10.
Section 113(3)	Paragraph (b) was repealed by the Health and Social Care Act 2008, section 95 and paragraph 45 of Schedule 5 and section 166 and Schedule 15(2).
Section 113(4)(aa) and (b)	Paragraph (aa) was inserted by the Public Services Ombudsman (Wales) Act 2005, section 39(1) and paragraphs 74 and 75 of Schedule 6(3).
Section 115(1)	
Section 115(2)	
Section 115(4)	
Section 115(5)	
Section 115(6)	
Section 195	
National Health Service (Wales) Act 2006(4)	
Section 187	
Section 206	
NHS Redress (Wales) Measure 2008(5)	
Section 1	
Section 2	

Section 3
Section 4
Section 5
Section 6
Section 7
Section 9
Section 11
Section 12

⁽¹⁾ 2003 c.43.

⁽²⁾ 2008 c.14

⁽³⁾ 2005 c.10.

⁽⁴⁾ 2006 c.42.

⁽⁵⁾ 2008 nawm 1.

CONSEQUENTIAL AND TRANSITIONAL
PROVISIONS

**Amendment of the National Health Service
(General Ophthalmic Services) Regulations 1986**

1.—(1) Schedule 1 (Terms of Service) to the National Health Service (General Ophthalmic Services) Regulations 1986(1) is amended as follows.

(2) Before paragraph 8A (Complaints) insert—

“Complaints and Concerns

8ZA

(1) A contractor must have in place—

(a) arrangements for the handling and consideration of complaints about any matter connected with the provision of general ophthalmic services which comply with the provisions of paragraph 8A for the handling and consideration of any complaints—

(i) which were made prior to 1 April 2011; and

(ii) in respect of which the complaints process has not yet been completed, and

(b) arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns notified on or after 1 April 2011. References in paragraphs 8B and 8C to a concern are to a concern notified in accordance with those Regulations.”.

(3) For the heading relating to paragraph 8A (Complaints) substitute —

“Complaints received prior to 1 April 2011”;

(4) For paragraph 8B substitute the following—

“Co-operation with investigations

8B

(1) A contractor must co-operate with any investigation of a complaint or a concern in relation to any matter reasonably connected to the contractor’s provision of general ophthalmic services undertaken by a “relevant body”, which includes—

(a) the Local Health Board;

- (b) the Welsh Ministers; or
- (c) the Public Services Ombudsman for Wales.

(2) The co-operation required by sub-paragraph (1) includes—

- (a) answering questions reasonably put to the contractor by a relevant body;
- (b) providing any information relating to the complaint or concern reasonably required by a relevant body; and
- (c) attending any meeting to consider the complaint or the concern (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given), if the contractor's presence is reasonably required by a relevant body.”.

(5) For the heading to paragraph 8C and paragraphs 8C(1) and (2), substitute the following—

“Complaints made against and concerns notified about ophthalmic medical practitioners

8C

(1) Where a contractor who, being an ophthalmic medical practitioner, also performs primary medical services under a GMS contract for any person for whom he provides general ophthalmic services, the complaints procedure or procedure for notifying concerns established and operated in accordance with the terms of that GMS contract shall apply in relation to any matter reasonably connected with his provision of general ophthalmic services as it applies as respects the provision of services under the GMS contract.

(2) Accordingly, any requirement as to co-operation with investigations of complaints or concerns by other bodies imposed on a GMS contractor under the term of his contract which gives effect to paragraph 95 of Schedule 2 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 also applies in relation to complaints or concerns about such matters.”.

Amendment of the National Health Service (Pharmaceutical Services) Regulations 1992

2.—(1) The National Health Service (Pharmaceutical Services) Regulations 1992(1) are amended as follows.

(1) S.I. 1992/662.

(2) In Part 4 of Schedule 2 (Clinical Governance and Complaints), for paragraph 28 (Complaints) substitute—

“Complaints and Concerns

28.

(1) A chemist must have in place—

(a) arrangements for the handling and consideration of complaints about any matter connected with the provision of pharmaceutical services which comply with the provisions of paragraph 10A and 10B of Schedule 2 to these Regulations as they apply on 31 March 2005 for the handling and consideration of any complaints—

(i) which were made prior to 1 April 2011; and

(ii) in respect of which the complaints process has not yet been completed, and

(b) arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns notified on or after 1 April 2011.”.

(3) In Part 6 of Schedule 2 (Terms of Service for Doctors who provide Pharmaceutical Services)—

(a) for the heading relating to paragraph 41 (Complaints procedures) substitute—

“Complaints and concerns”;

(b) in paragraph 41(1)(a) for “paragraph 90” substitute “paragraphs 89A and 90”;

(c) in paragraph 41(2) after “complaints” insert “or concerns notified”.

(4) In Schedule 2A (Terms of Service of Suppliers of Appliances)—

(a) after paragraph 21 (Home Local Health Board of bodies corporate) insert a new paragraph 21A—

“Concerns notified on or after 1 April 2011

21A

A supplier of appliances must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011.”;

(b) for the heading to paragraph 22 (Complaints), substitute—

“Complaints made prior to 1 April 2011”;

(c) for paragraph 22(1) substitute—

“A supplier of appliances must establish and operate in accordance with this paragraph a procedure (in this paragraph referred to as a “complaints procedure”) to deal with any complaints made prior to 1 April 2011 by or on behalf of any person to whom the supplier of appliances has provided pharmaceutical services.”.

Amendment of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

3.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(1) are amended as follows.

(2) In Schedule 6 (other contractual terms), before Part 6 (Complaints) insert—

“Part 5A

Concerns notified on or after 1 April 2011

89A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.”.

(3) In Part 6 of Schedule 6—

(a) for the heading relating to paragraph 90 (Complaints procedure), substitute—

“Complaints received prior to 1 April 2011”;

(b) in paragraph 90, for sub-paragraph (1), substitute the following—

“(1) In respect of any complaints made prior to 1 April 2011 in relation to any matter reasonably connected with the provision of services under the contract which have not been resolved by that date, the contractor must continue to deal with such complaints in accordance with the requirements of paragraphs 91 to 94 and 96.”;

(c) in paragraph 95 (co-operation with investigations)—

(i) after “complaint” in each place it occurs insert “or a concern notified in accordance with the National Health Service

(1) S.I. 2004/478 (W.48).

(Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011”;

(ii) for sub-paragraph (1)(a)(iii) substitute—

“(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; and”.

(4) In paragraph 98 of Part 7 of Schedule 6 (Dispute resolution: non-NHS contracts), for “complaints procedure pursuant to Part 6” substitute “procedures for notifying concerns or making complaints pursuant to Parts 5A and 6”.

(5) In Schedule 10 (information to be included in practice information leaflets), for paragraph 24 substitute—

”24

How patients may—

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 6;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of service.”.

Amendment of the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006

4.—(1) The National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(1), is amended as follows.

(2) In Schedule 3 (other contractual terms)—

(a) in Part 5 (Records, Information, Notifications and Rights of Entry), for paragraph 34(1)(c) (Patient Information) substitute —

“(c) information about the procedure for notifying concerns in accordance with Part 5A or, in respect of complaints made prior to 1 April 2011, the complaints procedure which it operates in accordance with Part 6 giving, in the case of a complaint under Part 6, the name and title of the person nominated in accordance with paragraph 50(2)(a) or, in the case of a notification of a concern, the name of the person designated as the senior investigations manager under regulation 8 of the National Health Service (Concerns,

(1) S.I. 2006/490 (W.59).

Complaints and Redress Arrangements)
(Wales) Regulations 2011.”.

(b) before Part 6 (Complaints) insert—

“Part 5A

Concerns notified on or after 1 April 2011

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.”.

(c) in Part 6 (Complaints)—

(i) for the heading relating to paragraph 47 (Complaints procedure), substitute—

“Complaints received prior to 1 April 2011”;

(ii) in paragraph 47 (Complaints procedure), for sub-paragraph (1)—

“As regards complaints relating to any matter reasonably connected with the provision of services under the contract which are received before 1 April 2011, the contractor must operate a complaints procedure which complies with the requirements of paragraphs 48 to 50 and 52. ”;

(iii) in paragraph 51 (co-operation with investigations)—

(aa) after “complaint” in each place it occurs insert “or concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ”; and

(bb) for sub-paragraph (1)(a)(iii) substitute—

“(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; and”;

(d) in Part 7 (Dispute resolution), in paragraph 54 (Dispute resolution: non NHS contracts), for “complaints procedure pursuant to Part 6” substitute “procedures for notifying concerns or making complaints pursuant to Parts 5A or 6”.

(3) In Schedule 4 (Patient Information Leaflet), for paragraph 17 substitute—

“17

How patients may—

- (1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 3;
- (2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or
- (3) comment on the provision of a service. ”.

Amendment of the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006

5.—(1) The National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(1) is amended as follows.

(2) In Schedule 3 (other contractual terms)—

- (a) in Part 5 (Records, Information, Notifications and Rights of Entry), for paragraph 35(1)(c) (Patient information) substitute—

“(c) information about the procedure for notifying concerns in accordance with Part 5A or, in respect of complaints made prior to 1 April 2011,, the complaints procedure which it operates in accordance with Part 6 giving, in the case of a complaint under Part 6, the name and title of the person nominated in accordance with paragraph 50(2)(a) or, in the case of a notification of a concern, the name of the person designated as the senior investigations manager under regulation 8 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.”;

- (b) before Part 6 (Complaints) insert—

“Part 5A

Concerns Notified On or After 1 April 2011

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.”;

(1) S.I. 2006/489 (W.58).

- (c) in Part 6 (complaints)—
 - (i) for the heading relating to paragraph 47 (Complaints procedure), substitute—
 - “**Complaints received prior to 1 April 2011**”;
 - (ii) in paragraph 47 (Complaints procedure), in sub-paragraph (1) for the words from “The contractor” to “the agreement” substitute—
 - “As regards complaints relating to any matter reasonably connected with the provision of services under the agreement which are received before 1 April 2011, the contractor must operate a complaints procedure”;
 - (iii) in paragraph 51 (Co-operation with investigations)—
 - (aa) after “complaint” in each place it occurs insert “or concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011”;
 - and
 - (bb) for sub-paragraph (1)(a)(iii) substitute—
 - “(iii) the Welsh Ministers; and
 - (iv) the Public Services Ombudsman for Wales; ”; and
 - (d) in Part 7 (Dispute Resolution), in paragraph 54 (dispute resolution: non NHS contracts), for “complaints procedure pursuant to Part 6” substitute “procedures for notifying concerns or making complaints pursuant to Parts 5A or 6”.

(3) In Schedule 4 (Patient Information Leaflet), for paragraph 16 substitute—

“16

How patients may—

- (1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 3;
- (2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or
- (3) comment on the provision of service.”.