
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

2010 No. (W.)

**NATIONAL HEALTH
SERVICE, WALES**

The National Health Service
(Concerns, Complaints and Redress
Arrangements) (Wales) Regulations
2010

EXPLANATORY NOTE

(This note is not part of the Regulations)

2010 No. (W.)

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The National Health Service
(Concerns, Complaints and Redress
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2010

Made ***

Coming into force ***

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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 2010 and they come into force on [.....] 2010.

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

Interpretation

2.—(1) In these Regulations—

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

“the Measure” (“...”) means the NHS Redress (Wales) Measure 2008(2);

“alternative dispute resolution” (“...”) means mediation, conciliation or facilitation;

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

“complaint” (“...”) means any expression of dissatisfaction;

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

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

(1) 2006 c.42.

(2) 2008 nawm 1.

“executive director” (“...”) means a member of the Board of a National Health Service Trust who is in the paid employ of that body;

“general dental services contractor” (“...”) means a person or body that 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” (“...”) means a person or body that has entered into a contract to provide general medical services with a Local Health Board in accordance with section 42 of the 2006 Act;

“incident concerning patient safety” (“...”) means any unexpected or unintended incident which did lead to or could have led to harm for a patient;

“independent provider” (“...”) 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” (“...”) 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 has agreed to provide 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” (“...”) means moderate or severe harm determined in accordance with guidance issued for the purpose of these Regulations by Welsh Ministers;

“non-executive director” (“...”) means a member of the Board of a National Health Service Trust who is not in the paid employ of that body;

“non-officer member” (“...”) means a member of the Board of a Local Health Board who is not in the paid employ of that body;

“officer member” (“...”) means a member of the Board of a Local Health Board who is in the paid employ of that body;

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

“primary care provider” (“...”) means a person or body who—

(a) is a general medical services contractor who has entered into a contract to provide primary medical services with a Local Health Board pursuant to section 42 of the 2006 Act ;

(b) provides primary medical services in accordance with arrangements made under section 41(2)(b) and 50 of the 2006 Act;

(c) is a general dental services contractor who has entered into a contract to provide primary dental services with a Local Health Board pursuant to section 57 of the 2006 Act;

(d) provides primary dental services in accordance with arrangements under section 64 of the 2006 Act;

(e) provides general ophthalmic services in accordance with section 71 of the 2006 Act;

(f) provides pharmaceutical services in accordance with 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 of the 2006 Act;

“qualifying liability” (“...”) means:

(1) 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, in consequence of any act or omission by a health care professional ; and

(2) which arises from the provision of qualifying services;

“relevant complaints procedure” (“...”) means—

(a) 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 directions—

(i) Directions to NHS Trusts and Local Health Boards on Hospital Complaints Procedures [signed on....];

(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...];

(iii) Miscellaneous Directions to Local Health Boards for Dealing with Complaints [signed on...];

(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(1);

(c) any complaints procedure 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 90 of Schedule 6 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(2);

(iii) paragraph 8A of Schedule 1 to the National Health Service (General Ophthalmic Services) Regulations 1986(3);

(iv) paragraph 47 of Schedule 3 to the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(4);

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

“responsible body” (“...”) means—

- (a) a Welsh NHS body;
- (b) a primary care provider; or
- (c) an independent provider;

“responsible officer” (“...”) means the person designated in accordance with regulation 7(1);

“senior investigations manager” (“...”) means the person designated in accordance with regulation 8(1);

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

(1) S.I. 1992/662.
(2) S.I. 2004/478 (W.48).
(3) S.I. 1986.975.
(4) S.I. 2006/490 (W.59).
(5) S.I. 2006/489 (W.58).

“Welsh NHS body” (“...”) 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” (“...”) 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 (“ ”) 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 (“ ”) 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 for the handling and investigation of concerns set up under these Regulations must be such as to ensure that—

- (a) there is a single point of entry for the receiving of concerns;
- (b) concerns are dealt with efficiently and openly;
- (c) concerns are properly investigated;
- (d) provision should be made to determine 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 —
 - (i) the availability of assistance to enable them to pursue their concern;
 - (ii) advice upon where they may obtain such assistance, if it is required; and
 - (iii) the name of the person who will act as their contact throughout the handling of their concern;

(1) 1971 c.80.

- (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 there is a qualifying liability arising from the provision of qualifying services;
- (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, if necessary, 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 the arrangements it has in place 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 in tort, claims management reporting are dealt with under a single governance umbrella.

(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 appoint 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 dealing with 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 investigation and resolution 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 investigation or resolution of concerns.

(2) The responsible body must ensure that the senior investigations manager appointed by that body has a proper and 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 deal with a concern in accordance with the arrangements for dealing with concerns set out in these Regulations if it is notified on or after the [insert cif date] and is—

- (a) notified 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 receives or has received services from a responsible body;
- (b) any person who is affected, or likely to be affected by the action, omission or decision of the responsible body which is the subject of the concern;
- (c) a non-officer member or a non-executive director of the responsible body;
- (d) a member of the staff of the 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
- (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 that the child may reasonably require in order to pursue the concern.

(5) This paragraph applies where—

(1) 2005 c.9.

(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 (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 reasonable and 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 includes a reference to a representative of that person.

Matters about which concerns may be notified

13.—(1) 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 arrangement with the Local Health Board.

Matters excluded from consideration under the arrangements

14.—(1) The following are matters 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 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

(1) in accordance with the Public Services Ombudsman (Wales) Act 2005. 2005 c.10.

(2) 2000 c.36.

with sub-paragraph (f) unless the responsible body considers that it is reasonable to re-open 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 **[DN – insert coming into force/application date]**;
- (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 is a concern 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 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 12 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 3 or more years after the date on which the matter which is the subject of the concern occurred or, if later, 3 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) above, references 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 to confirm the verbal withdrawal of a concern.

(3) Where the responsible body has confirmed the withdrawal of a concern in accordance with paragraph (2), it may nevertheless continue to investigate any issues raised by the concern in accordance with Part 5, should the responsible body consider that it is reasonable and 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 the concern has raised concerns 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 the patient or, in accordance with regulation 12, their representative —

- (a) within 2 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 2 working days of receipt of the consent mentioned in 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 investigation of the concerns; 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 (2) 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 of 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 consideration of the concern which is reasonably requested by another body; and
 - (c) to attend, or ensure that it is represented at any meeting reasonably required in connection with the consideration of the concern.

Concerns involving primary care providers

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

- (a) notified to a Local Health Board in accordance with arrangements for dealing with concerns made under these Regulations on or after [insert cif];
- (b) about the services provided by a primary care provider under a contract or arrangements with a Local Health Board or National Health Service Trust ; 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 in accordance with regulation 18 by or on behalf of a person who receives or has received services from a primary care provider it must determine, in accordance with paragraph (2) whether the concern is one which it is appropriate for it to consider .

(2) The Local Health Board must decide whether, in its opinion, the concern that has been notified to it 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.

(3) Before making a decision the Local Health Board must ask 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.

(4) 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.

(5) 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 matters raised by the concern.

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

20.—(1) Where a Local Health Board receives a concern referred in accordance with regulation 18 by a primary care provider it must determine, in accordance with paragraph (2), whether the concern is one that it is appropriate for it to consider.

(2) The Local Health Board must decide whether, in its opinion, the concern that has been notified to it 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.

(3) 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 a concern if it decides in accordance with paragraph (2) that it is appropriate for it to do so.
- (4) If a response has been issued by the provider in accordance with regulation 24, the Local Health Board must not consider the concern.
- (5) 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 in accordance with regulations 19 and 20

- 21.**—(1) If the Local Health Board decides, in accordance with regulation 19(2) or 20(2) that it is appropriate for it to deal with a concern notified in accordance with regulation 18 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(2) or 20(2) that it is more appropriate for the concern to be dealt with by the primary care provider the Local Health Board must—
- (a) advise the person who notified the concern and the primary care provider;
 - (b) when the primary care provider receives the notification issued by the Local Health Board under sub-paragraph (a)—
 - (i) the primary care provider must handle the concern in accordance with these Regulations; and
 - (ii) the person who notified the concern is deemed to have notified the concern to the primary care provider in accordance with these Regulations.
- (3) The time limit for notifying a decision made under regulation 19(2) or 20(2) is five working days from receipt of confirmation of the matters outlined in regulation 19(3) or 20(3).
- (4) A Local Health Board must give reasons for its decision under regulation 19(2) or regulation 20(2).

(5) When a Local Health Board receives a concern notified by or on behalf of a person who receives 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 take any concern about the decision of the Local Health Board to the Public Services Ombudsman for Wales.

(6) 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(5) 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 2 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) 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 that is likely to be sent to that person.

(4) If the person who notifies the concern does not accept the offer of a discussion under paragraph (3), 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.

(5) 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 resolve those matters thoroughly, speedily and efficiently, having particular regard to:

- (a) the carrying out an initial grading assessment of the concern to assist in its determination of the level 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 the way in which 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) the consideration of whether the person investigating the matters raised by the concern requires independent clinical or other advice;
- (f) the consideration of whether the concern may be capable of resolution by making use of alternative dispute resolution;
- (g) the making of decisions about root cause;
- (h) any guidance issued by the Welsh Assembly Government with respect to the exercise of the responsible body's functions; and
- (i) where the responsible body is a Welsh NHS body -
 - (i) the likelihood of any qualifying liability arising from the provision of qualifying services;
 - (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 is not under a duty to consider the matters in paragraph (1)(i) above.

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 notification of 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 notified in the concern;
- (b) describes the investigation undertaken in accordance with regulation 23;
- (c) contains copies of any expert opinion 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 take 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) A responsible body must take all reasonable steps to send a response to the person who notified the concern within 30 working days beginning on the day upon which it received notification of the concern.

(3) If a responsible body is unable to provide a response within 30 working days 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 response as soon as reasonably practicable and within 6 months beginning

on the day upon which it received notification of the concern.

(4) If exceptional circumstances mean that the 6 month period in paragraph (3)(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 arising from the provision of qualifying services 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 arising from the provision of qualifying services exists.

Response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability in tort arising from the provision of qualifying services

26.—(1) Where following an investigation under regulation 23 a responsible body that is a Welsh NHS body considers that there is or there may be a qualifying liability in tort arising from the provision of qualifying services, that Welsh NHS body will 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 in tort;
- (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 arising out of the provision of qualifying services 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 take the concern to the Public Services Ombudsman for Wales;
- (j) offers the person notifying the concern 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 30 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 in accordance with paragraph (2) as soon as reasonably practicable and within 6 months beginning with the day upon which it received notification of the concern. If exceptional circumstances mean that the 6 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.

(4) The investigation report referred to in regulation 31 must be provided to the person who notified the concern as soon as reasonably practicable and not later than 12 months from the date that the Welsh NHS body received notification of the concern. If exceptional circumstances mean that the 12 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 investigation report may be expected.

Form of redress

27.—(1) Redress under these Regulations 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 can 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 arising from the provision of qualifying services by way of financial compensation in which the sum does not exceed £40,000

(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) 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 in tort arising from the provision of qualifying services, the Welsh NHS body may give consideration to making an offer of settlement in the usual way outwith the provisions of these Regulations.

(4) The assessment of damages for pain, suffering and loss of amenity is calculated on the common law basis. However, Welsh Ministers may from time to time issue, or arrange for the issue of, 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 these Regulations.

Suspension of the limitation period

30.—(1) During the period in which a liability is the subject of an application for redress under these Regulations, 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 these Regulations, 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 a Welsh NHS body in accordance with regulation 11; and
- (b) subject to paragraphs (3) and (4), up to and including the time 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(1)(d) 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 a subject of an application for redress 9 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(1)(e), limitation, if limitation is an issue, is suspended until a settlement is reached which receives the approval of the court.

Investigation report

31.—(1) A Welsh NHS body must ensure that the findings of the investigation of a concern in which a

(1) 1980 c.58.

person is seeking redress under these Regulations are recorded in an investigation report.

(2) Unless paragraph (3) applies, the Welsh NHS body must provide the person who is seeking redress under these Regulations with a copy of the investigation report within the time frame set out in regulation 26(4).

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

- (a) before an offer of redress under these Regulations is made or if the investigation of redress in accordance with these Regulations is for any reason terminated; or
- (b) where the report contains information likely to cause the patient or other applicant for redress significant harm or distress.

Legal advice and instruction of clinical experts

32.—(1) Where a Welsh NHS body has determined that a qualifying liability arising from the provision of qualifying services 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 these Regulations in accordance with the following provisions of this regulation; and
- (b) if a clinical 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 are included in a specialist list or panel compiled by such person or body specified by the Welsh Ministers in a list to be published in alongside these Regulations.

(3) A Welsh NHS body must specify that legal advice will be available in relation to the following matters—

- (a) the joint instruction of clinical 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 and clinical advice must be borne in its entirety by the Welsh NHS body in accordance with an agreed framework of financial reimbursement which will be published and kept under

review by a Welsh NHS body directed to perform this function by Welsh Ministers.

Redress – making of an offer of compensation

33.—(1) Where a Welsh NHS body determines to make an offer of redress by way of financial compensation or entry into a contract to provide care or treatment or both, it must—

- (a) notify the offer to the person who notified the concern within 12 months of the date on which the concern was notified to the Welsh NHS body. If exceptional circumstances mean that the 12 month period cannot be adhered to, the NHS body must advise the person who notified the concern, or his/her, legal representative, of the reasons for the delay and when an offer will be made;
- (b) advise that person or his or her legal representative that he or she must respond to the offer of settlement within 6 months of the date that it is made;
- (c) subject to paragraph (c), advise that if, as a result of exceptional circumstances, it will not be possible to respond to the offer of settlement in 6 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, a response is required within 9 calendar months of the date of the offer as that is the time when, in accordance with regulation 30(3), limitation starts to run;
- (e) advise 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

(1) 2005 c.9.

body must pay the reasonable legal costs associated with obtaining such approval.

PART 7

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

Interpretation of this Part

34.—(1) “A contracting person or body” (“ ”) means, with the exception of primary care providers, a body or person in England or Wales providing, or arranging for the provision of, services whose provision is the subject of arrangements with a Welsh NHS body.

(2) “A contracting person or body in Scotland or Northern Ireland” (“ ”) means, with the exception of primary care providers, a person or body in Scotland or Northern Ireland 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, “primary care provider” (“ ”) also includes a person or body who—

- (a) has entered into a general medical services contract with a Primary Care Trust in accordance with section 84 of the NHS Act 2006⁽¹⁾;
- (b) provides primary medical services in accordance with arrangements made under section 83(2)(b) or 92 of the NHS Act 2006;
- (c) has entered into a general dental services contract with a Primary Care Trust in accordance with section 100 of the NHS Act 2006;
- (d) provides primary dental services in accordance with arrangements made under section 107 of the NHS Act 2006;
- (e) has entered into a general ophthalmic services contract with a Primary Care Trust

(1) 2006 c. 41.

in accordance with section 117 of the NHS Act 2006;

- (f) provides pharmaceutical services in accordance with arrangements made under section 126 of the NHS Act 2006;
- (g) provides additional pharmaceutical services in accordance with arrangements made under section 127 of the NHS Act 2006;
- (h) provides local pharmaceutical services in accordance with an LPS scheme established under paragraph 1 of Schedule 12 to the NHS Act 2006;
- (i) provides primary medical services in accordance with a general medical services contract in Scotland;
- (j) provides primary medical services in accordance with arrangements made under section 17C of the NHS Scotland Act 1978(1);
- (k) provides services in Scotland under a HBPMS contract, that is a person or body providing primary medical services under an arrangement with a Scottish Health Board in accordance with section 2C(2) of the NHS Scotland Act 1978, other than in accordance with a general medical services contract in Scotland or arrangements made under section 17C of the Scotland Act 1978;
- (l) is a dental practitioner who provides general dental services in accordance with arrangements made under section 25 of the NHS Scotland Act 1978;
- (m) is a person who provides personal dental services in Scotland in accordance with a pilot scheme;
- (n) is an ophthalmic optician or medical practitioner who provides general ophthalmic services in accordance with arrangements made under section 26 of the NHS Scotland Act 1978;
- (o) is a person who provides pharmaceutical services in accordance with arrangements made under section 27 of the NHS Scotland Act 1978; or
- (p) is a person or body who provides such services in Northern Ireland.

(4) “Relevant complaints procedure” (“ ”) means a complaints procedure that a contracting person or body must follow on receipt of a concern.

(1) 1978 asp. [].

(5) “Person who notified a concern” (“ ”) means, depending on the context, the person who notified a concern to a contracting person or body or a contracting person or body in Scotland or Northern Ireland.

Circumstances in which a contracting person or body must consider whether or not redress may apply.

35.—(1) If a contracting person or body receives notification of a concern under a relevant complaints procedure that relates to a service or services which it has provided, or arranged for the provision of, under arrangements with a Welsh NHS body, that contracting person or body must when considering the concern in accordance with that complaints procedure give consideration to whether or not the concern involves a qualifying liability arising from the provision of qualifying services for which redress may be available.

(2) If a contracting person or body concludes that a qualifying liability exists or may exist and that redress may be available, that person or body must take the steps outlined in regulation 36.

Steps to be taken where a contracting person or body considers that a qualifying liability arising from the provision of qualifying services exists or may exist

36. The contracting person or body must notify the Welsh NHS body with whom they have entered into an arrangement that it is of the view that a qualifying liability in respect of qualifying services 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 the contracting person or body believes that there is or there may be a qualifying liability;
- (e) the date that the concern was received by the contracting person or body; and
- (f) such other information or assistance as the Welsh NHS body with whom the contracting

person or body has entered into an arrangement with may reasonably require.

Action to be taken by a Welsh NHS body on receipt of a notification from a contracting person or body in accordance with regulation 36.

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

(2) It must also advise the person who notified the concern to the contracting person or body that the concern has now been passed to it to consider, in accordance with the provisions of these Regulations, whether or not a qualifying liability arising from the provision of qualifying services exists.

(3) A Welsh NHS body must, in accordance with the provisions of this Part, determine whether or not a qualifying liability arising from the provision of qualifying services exists and it must, in accordance with the provisions of this Part, 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 contracting person or body in Scotland or Northern Ireland.

38.—(1) A Welsh NHS body must acknowledge receipt of a notification made by a contracting person or body in Scotland or Northern Ireland.

(2) It must also advise the person who notified the concern that the concern has now been passed to it to consider, in accordance with the provisions of these Regulations, whether or not a qualifying liability arising from the provision of qualifying services exists.

(3) A Welsh NHS body must, in accordance with the provisions of this Part, determine whether or not a qualifying liability arising from the provision of qualifying services exists and it must, in accordance with the provisions of this Part, determine whether or not an offer of redress should be made to the patient.

Duty of Welsh NHS body to conduct an investigation.

39. On receipt of a notification from a contracting person or body or a contracting person or body in Scotland or Northern Ireland, 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).

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 arising from the provision of qualifying services.

40.—(1) Where following an investigation under regulation 39 a Welsh NHS body considers that there is or there may be a qualifying liability in tort arising from the provision of qualifying services, the 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 39;
- (c) describes why, in the opinion of the Welsh NHS body, there is or there may be a qualifying liability in tort arising from the provision of qualifying services;
- (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 arising out of the provision of qualifying services 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;
- (i) contains details of the right to take 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 notifying the concern 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 50 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 in accordance with paragraph (2) as soon as reasonably practicable and within 6 months beginning with the day upon which it received notification of the concern. If exceptional circumstances mean that the 6 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.

(4) The investigation report referred to in regulation 46 must be provided to the person who notified the concern as soon as reasonably practicable and not later than 12 months from the date that the Welsh NHS body received notification of the concern. If exceptional circumstances mean that the 12 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 investigation report may be expected.

Response to an investigation under regulation 39 where a Welsh NHS body is of the opinion that there is no qualifying liability arising from the provision of qualifying services.

41. Where following an investigation in accordance with regulation 39, a Welsh NHS body is of the opinion that the concern notified in accordance with regulation 36 or by a contracting person or body in Scotland or Northern Ireland does not involve a qualifying liability in tort arising from the provision of qualifying services, 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 take 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 contracting person or body or contracting person or body in Scotland or Northern Ireland.

Form of redress

42. Redress under these Regulations 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 can 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 these Regulations must cease and the Welsh NHS body must advise the person who notified the concern and the contracting person or body or contracting person or body in Scotland or Northern Ireland accordingly.

Redress – financial compensation

44.—(1) A Welsh NHS body may make an offer of redress for a qualifying liability arising from the provision of qualifying services by way of financial compensation in which the sum does not exceed £40,000.

(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. However, Welsh Ministers may from time to time issue, or arrange for the issue of, 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 these Regulations.

(5) In respect of concerns notified by a contracting person or body in accordance with regulation 36, a Welsh NHS body must, before making an offer of financial compensation in accordance with this regulation, consult with, and take into consideration the views of the contracting person or body.

Suspension of the limitation period

45.—(1) During the period in which a liability is the subject of an application for redress under these Regulations, 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 these Regulations, 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 a contracting person or body or a contracting person or body in Scotland or Northern Ireland ;
- (b) subject to paragraphs (3) and (4), 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(1)(d) 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 a subject of an application for redress 9 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(1)(e), limitation, if limitation is an issue, is suspended until a settlement is reached which receives the approval of the court.

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 these Regulations are recorded in an investigation report.

(1) 1980 c.58.

(2) Unless paragraph (3) applies, the Welsh NHS body must provide the person who is seeking redress under these Regulations with a copy of the investigation report within the time frame set out in regulation 40(4).

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

- (a) before an offer of redress under these Regulations is made or if the investigation of redress in accordance with these Regulations is for any reason terminated; or
- (b) where the report contains information likely to cause the patient or other applicant for redress significant harm or distress.

Legal advice and instruction of clinical experts

47.—(1) Where a Welsh NHS body has determined that a qualifying liability arising from the provision of qualifying services 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 these Regulations in accordance with the following provisions of this regulation; and
- (b) if a clinical 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 are included in a specialist list or panel compiled by such person or body specified by the Welsh Ministers in a list to be published alongside these Regulations.

(3) A Welsh NHS body must specify that legal advice will be available in relation to the following matters—

- (a) the joint instruction of clinical 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 a contracting person or body, the cost of such legal and clinical advice must be borne in its entirety by the Welsh NHS body in accordance with an agreed framework of financial reimbursement which will be published and kept under

review by a Welsh NHS body directed to perform this function by Welsh Ministers.

Redress – making of an offer of compensation

48.—(1) Where a Welsh NHS body determines to make an offer of redress by way of financial compensation or entry into a contract to provide care or treatment or both, it must—

- (a) notify the offer to the person who notified the concern within 12 months of the date on which the concern was notified to the Welsh NHS body. If exceptional circumstances mean that the 12 month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern, or his/her, legal representative, of the reasons for the delay and when an offer will be made;
- (b) advise that person or his or her legal representative that he or she must respond to the offer of settlement within 6 months of the date that it is made. However, subject to paragraph (c), the Welsh NHS body must advise that if, as a result of exceptional circumstances, it will not be possible to respond to the offer of settlement in that timeframe, the Welsh NHS body must be advised of the reasons for the delay in responding and when a response will be submitted;
- (c) advise a person or his or her legal representative that if an extension of time is sought to respond to an offer of settlement, a response is required within 9 calendar months of the date of the offer as that is the time when, in accordance with regulation 45(3), limitation starts to run;
- (d) advise 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;
- (e) 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

(1) 2005 c.9.

- (f) 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 service 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 issues 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 subject matter and the outcome of each concern; and
- (c) where the responsible body informed the person who notified the concern of—

- (i) the likely period within which a response would be issued in accordance with regulation 22(3); or
- (ii) any amendment to that period,
whether a response detailing the outcome of the investigation of the concern was sent to the person who notified concern within that period, or any amended 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 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 referred 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) Where paragraph (2) applies to a responsible body, the responsible body 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 that have been made in accordance with the following provisions—

- (a) sections 12(3), 19 and 204(1) of the 2006 Act;
- (b) section 9(2)(c) of the National Health Service (Primary Care) Act 1997⁽¹⁾; and
- (c) section 1A of the Hospital Complaints Procedure Act 1985⁽²⁾,

which are revoked by regulation 35.

(2) Where before **[insert cif/date of application of new regs]**—

- (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,

that review panel must be appointed, conduct its investigation and make a report in accordance with the former complaints provisions.

(4) Where a complaint, the subject matter of which occurred before **[insert cif/date from which the new arrangements will apply]**—

- (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,

⁽¹⁾ 1997 c.46.
⁽²⁾ 1985 c.42.

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

Revocations

53.Subject to regulation 34, the following directions made under the provisions listed in regulation 34(1)(a) are revoked:

- (a) the Directions to NHS Trust and Local Health Boards on Hospital Complaints Procedures, made on [...];
- (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 [...]; and
- (c) Miscellaneous Directions to Local Health Boards for Dealing with Complaints, made on [...].

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 2(1)	
Section 187	
NHS Redress (Wales) Measure 2008(5)	
Section 1	
Section 2	

Section 3
Section 4
Section 5
Section 6
Section 7
Section 8
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.

SCHEDULE 2 Regulation 36

CONSEQUENTIAL AND TRANSITIONAL PROVISION

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 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 service which comply with the provisions of paragraph 8A for the handling and consideration of any complaints—

(i) which were made prior to **[insert coming into force date/date from which regs will apply]**; 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 2010, for the handling and considerations of any concerns notified on or after **[insert the coming into force date/date from which the regs will apply]**.”.

(3) 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 the contractor’s provision of general ophthalmic services undertaken by a “relevant body”, which include—

(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;
- (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 present is reasonably required by a relevant body.”.

(4) For the heading to paragraph 8C, substitute the following—

“Complaints and concerns”;

(5) In paragraph 8C—

- (a) in sub-paragraph (1) for “the complaints procedure” substitute “procedures for notifying concerns of making complaints”;
- (b) in sub-paragraph (2) for “complaints” substitute “complaints or concerns”.

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.

(2) In Part 4 of Schedule 2 (clinical governance and complaints), for paragraph 28 (complaints) substitute—

“Complaints and Concerns

28.

(1) A pharmacist 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 these Regulations as they apply on 31 March 2005 for the handling and consideration of any complaints—
 - (i) which were made prior to **[insert coming into force date/date from which regs will apply]**; 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 2010, for

⁽¹⁾ S.I. 1992/662.

the handling and considerations of any concerns notified on or after **[insert the coming into force date/date from which the regs will apply]**.”.

(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 procedure) 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”.

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.... [inset cif date/date from which regs will apply]

89A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2010 to deal with any concerns notified on or after **[insert cif date/date from which regs will apply]** 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 ...[inset the cif date/date from which the regulations will apply]”;

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

“(1) In respect of any complaints made prior to **[insert cif date/date from which regulations will apply]** 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

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

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 concern”;

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

“(iii) the Welsh Ministers; and

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

(4) In Part 7 (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), in paragraph 24, after “make a complaint” insert “, notify a concern”.

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), in paragraph 34(1)(c) (patient information) for “complaints procedure which it operates in accordance with Part 6” substitute “procedure for notifying concerns or complaints procedure which it operates in accordance with Parts 5A or 6”;

(b) before Part 6 (complaints) insert—

“Part 5A

Complaints Received on or After[Insert coming into force date or date from which they will apply]

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2010 to deal with any concerns notified on or after **[insert coming into force date or date from which they will apply]** about any matter reasonably connected with the provision of services under the contract.”.

(c) in Part 6 (complaints)—

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

- (i) in paragraph 47 (complaints procedure), in sub-paragraph (1) for the words from “The contractor” to “the contract” substitute—

“As regards complaints relating to any matter reasonably connected with the provision of services under the contract which are received before **[insert the cif/date upon which the regulations will apply]**, the contract must operate a complaints procedure”;

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

- (aa) after “complaint” in each place it occurs insert “or concern”;
- 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), in paragraph 17, after “make a complaint” insert “, notify a concern”.

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), in paragraph 35(1)(c) (patient information”) for “complaints procedure which it operates in accordance with Part 6” substitute “procedure for notifying concerns or complaints procedure which it operates in accordance with Parts 5A or 6”;

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

“Part 5A

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

Complaints Received on or After[Insert coming into force date or date from which they will apply]

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2010 to deal with any concerns notified on or after **[insert coming into force date or date from which they will apply]** about any matter reasonably connected with the provision of services under the contract.”;

(c) in Part 6 (complaints)—

(i) 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 **[insert the cif/date upon which the regulations will apply]**, the contractor must operate a complaints procedure”;

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

(aa) after “complaint” in each place it occurs insert “or concern”;
and

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

(iii) “(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), in paragraph 16, after “make a complaint” insert “, notify a concern”.