WELSH STATUTORY INSTRUMENTS

2011 No. 704 (W.108)

NATIONAL HEALTH SERVICE, WALES

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

Made - - - - 8 March 2011
Coming into force in accordance with the provisions of regulation 1(2)

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.

PART 1

GENERAL

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;

(**1**) 2006 c. 42.

"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;

"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(**2**);

(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(**3**);

(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(**4**);

(iv) paragraph 8A of Schedule 1 to the National Health Service (General Ophthalmic Services) Regulations 1986(**5**);

(**2**) 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.
(**3**) S.I.1992/662.
(**4**) S.I. 2004/478 (W.48).
(**5**) S.I. 1986/975.

(v) paragraph 47 of Schedule 3 to the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(**6**);

(vi) paragraph 47 of Schedule 3 to the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(**7**);

"responsible body" ("*corff cyfrifol*") means—

(a) a Welsh NHS body;

(b) a primary care provider; or

(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(**8**).

(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—

(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;

(**6**) S.I. 2006/490 (W.59).
(**7**) S.I. 2006/489 (W.58).
(**8**) 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 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—