
WELSH STATUTORY INSTRUMENTS

2002 No. 325

Private and Voluntary Health Care (Wales) Regulations 2002

**PART I
GENERAL**

Citation, commencement and application

1.—(1) These Regulations may be cited as the Private and Voluntary Health Care (Wales) Regulations 2002 and shall come into force on 1st April 2002.

(2) These Regulations apply in relation to establishments, as defined in regulation 2(1), in Wales.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” (“*y Ddeddf*”) means the Care Standards Act 2000;

“appropriate office” (“*swyddfa briodol*”) means in relation to an establishment—

(a) if an office has been specified under paragraph (2) for the area in which the establishment is situated, that office;

(b) in any other case, any office of the National Assembly;

“dentist” (“*deintydd*”) means a person registered in the dentists register under the Dentists Act 1984(1);

“establishment” (“*sefydliad*”) means an independent hospital, including an independent hospital in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983(2), or an independent clinic;

“general practitioner” (“*ymarferydd*”) means a medical practitioner who—

(a) provides general medical services within the meaning of Part II of the NHS Act;

(b) performs personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997(3); or

(c) provides services which correspond to services provided under Part II of the NHS Act, otherwise than in pursuance of that Act;

“health care professional” (“*proffesionolyn gofal iechyd*”) means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(4) applies, or who is a clinical psychologist or child psychotherapist and “health care profession” shall be construed accordingly;

(1) 1984 c. 24.

(2) 1983 c. 20.

(3) 1997 c. 46.

(4) 1999 c. 8.

“medical device” (“*dyfais feddygol*”) has the same meaning as in the Medical Devices Regulations 1994⁽⁵⁾;

“medical practitioner” (“*ymarferydd meddygol*”) means a registered medical practitioner⁽⁶⁾;

“midwife” (“*bydwraig*”) means a registered midwife⁽⁷⁾ who has notified her intention to practise to the local supervisory authority in accordance with any rules made under section 14(1)(b) of the Nurses, Midwives and Health Visitors Act 1997⁽⁸⁾;

“National Assembly” (“*Cynulliad Cenedlaethol*”) means the National Assembly for Wales;

“the NHS Act” (“*Deddf y GIG*”) means the National Health Service Act 1977⁽⁹⁾;

“organisation” (“*corff*”) means a body corporate ;

“patient” (“*claf*”), in relation to an establishment , means a person for whom treatment is provided in or for the purposes of the establishment;

“patients' guide” (“*arweiniad y cleifion*”) means the guide compiled in accordance with regulation 6;

“practising privileges” (“*breintiau ymarfer*”), in relation to a medical practitioner, refers to the grant to a person who is not employed in an independent hospital of permission to practise in that hospital;

“registered manager” (“*rheolwr cofrestredig*”), in relation to an establishment, means a person who is registered under Part II of the Act as the manager of the establishment;

“registered person” (“*person cofrestredig*”), in relation to an establishment, means any person who is the registered provider or the registered manager of the establishment;

“registered provider” (“*darparnydd cofrestredig*”), in relation to an establishment, means a person who is registered under Part II of the Act as the person carrying on the establishment;

“responsible individual” (“*unigolyn cyfrifol*”) shall be construed in accordance with regulation 9;

“specialist medical register” (“*cofrestr feddygol arbenigol*”) means the register of specialists kept and published by the General Medical Council in accordance with the European Specialist Medical Qualifications Order 1995⁽¹⁰⁾;

“statement of purpose” (“*datganiad o ddiben*”) means the written statement compiled in accordance with regulation 5;

“treatment” (“*triniaeth*”) includes palliative care, nursing and listed services, within the meaning of section 2 of the Act⁽¹¹⁾.

(2) The National Assembly may specify an office controlled by it as the appropriate office in relation to establishments situated in a particular area of Wales.

(3) In these Regulations, a reference—

- (a) to a numbered regulation or Schedule is to the regulation in, or Schedule to, these Regulations bearing that number;
- (b) in a regulation or Schedule to a numbered paragraph, is to the paragraph in that regulation or Schedule bearing that number;

(5) S.I.1994/3017.

(6) See the Interpretation Act 1978 (c. 30), Schedule 1, as amended by the Medical Act 1983 (c. 54), section 56(1), Schedule 5, paragraph 18.

(7) See the Interpretation Act 1978, Schedule 1. A definition of “registered” in relation to midwives was inserted by the Nurses, Midwives and Health Visitors Act 1979 (c. 36), Schedule 7, paragraph 30.

(8) 1997 c. 24.

(9) 1977 c. 49.

(10) S.I. 1995/3208, as amended by S.I. 1997/2928, 1999/1373 and 3154.

(11) See section 2(7).

(c) in a paragraph to a lettered or numbered sub-paragraph is to the sub-paragraph in that paragraph bearing that letter or number.

(4) In these Regulations, unless the contrary intention appears, references to employing a person include employing a person whether under a contract of service or a contract for services and references to an employee or to a person being employed shall be construed accordingly.

Meaning of “independent hospital”

3.—(1) Subject to paragraph (2), for the purposes of section 2 of the Act, “listed services” include treatment using any of the following techniques or technology—

- (a) a Class 3B or Class 4 laser product, as defined in Part I of British Standard EN 60825-1 (Radiation safety of laser products and systems)(**12**);
- (b) an intense light, being broadband non-coherent light which is filtered to produce a specified range of wavelengths, such filtered radiation being delivered to the body, with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues;
- (c) haemodialysis or peritoneal dialysis;
- (d) endoscopy;
- (e) hyperbaric oxygen therapy, being the administration of pure oxygen through a mask to a patient who is in a sealed chamber which is gradually pressurised with compressed air, except where the primary use of that chamber is—
 - (i) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997(**13**) or regulation 8 or 12 of the Work in Compressed Air Regulations 1996(**14**); or
 - (ii) otherwise for the treatment of workers in connection with the work which they perform; and
- (f) *in vitro* fertilisation techniques, being treatment services for which a licence may be granted under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990(**15**).

(2) “Listed services” shall not include treatment using the following techniques or technology—

- (a) treatment for the relief of muscular and joint pain using an infra-red heat treatment lamp;
- (b) treatment using a Class 3B laser product where such treatment is carried out by or under the supervision of a health care professional;
- (c) the use of an apparatus (not being an apparatus falling within paragraph (1)(b)) for acquiring an artificial suntan, consisting of a lamp or lamps emitting ultraviolet rays.

(3) For the purposes of section 2 of the Act, establishments of the following descriptions are excepted from being independent hospitals—

- (a) an establishment which is a hospital by virtue of section 2(3)(a)(i) solely because its main purpose is to provide medical or psychiatric treatment for illness or mental disorder but which provides no overnight beds for patients;
- (b) an establishment which is a service hospital within the meaning of section 13(9) of the Armed Forces Act 1981(**16**);

(12) Copies of BS EN 60825-1 may be obtained from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.

(13) S.I. 1997/2776.

(14) S.I. 1996/1656.

(15) 1990 c. 37.

(16) 1981 c. 55.

- (c) an establishment which is, or forms part of, a prison, remand centre, young offender institution or secure training centre within the meaning of the Prison Act 1952(17);
- (d) an establishment which is an independent clinic by virtue of regulation 4;
- (e) an establishment (not being a health service hospital) which has as its sole or main purpose the provision by a general practitioner or practitioners of general medical services within the meaning of Part II of the NHS Act or personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and such an establishment shall not become an independent hospital as the result of the provision of listed services to a patient or patients by such a general practitioner or practitioners;
- (f) the private residence of a patient or patients in which treatment is provided to such patient or patients but to no-one else;
- (g) sports grounds and gymnasias where health care professionals provide treatment to persons taking part in sporting activities and events; and
- (h) a surgery or consulting room, not being part of a hospital, where a medical practitioner provides medical services solely under arrangements made on behalf of the patients by their employer or another person.

(4) Sub-section (7) of section 2 of the Act shall be modified by adding at the end of paragraph (e) (cosmetic surgery) the following—

“other than—

- (i) ear and body piercing;
- (ii) tattooing;
- (iii) the subcutaneous injection of a substance or substances into the skin for cosmetic purposes; and
- (iv) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.”.

Meaning of “independent clinic”

4.—(1) For the purposes of the Act, establishments of the following kinds are independent clinics—

- (a) a walk-in centre, in which one or more medical practitioners provide services of a kind which, if provided in pursuance of the NHS Act, would be provided as general medical services under Part II of that Act; and
- (b) a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the NHS Act provides medical services of any kind (including psychiatric treatment) otherwise than under arrangements made on behalf of the patients by their employer or another person.

(2) Where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical practitioners shall be regarded as carrying on a separate independent clinic unless they are in practice together.

(17) 1952 c. 52. See section 53(1) and section 43, as substituted by the Criminal Justice Act 1982 (c. 48) section 11 and amended by the Criminal Justice Act 1988 (c. 33), the Criminal Justice and Public Order Act 1994 (c. 33) and the Criminal Justice Act 1991 (c. 53).

Statement of purpose

5.—(1) The registered person shall compile in relation to the establishment a statement on paper (in these Regulations referred to as “the statement of purpose”) which shall consist of a statement as to the matters listed in Schedule 1.

(2) The registered person shall provide a copy of the statement of purpose to the appropriate office of the National Assembly and shall make a copy of it available upon request for inspection at any reasonable time by every patient and any person acting on behalf of a patient.

(3) Subject to paragraph (4) the registered person shall ensure that the establishment is conducted in a manner which is consistent with its statement of purpose.

(4) Nothing in paragraph (3), regulation 14(1) or 24(1) and (2) shall require or authorise the registered person to contravene, or not comply with—

- (a) any other provision of these Regulations; or
- (b) the conditions for the time being in force in relation to the registration of the registered person under Part II of the Act.

Patients' guide

6.—(1) The registered person shall produce a written guide to the establishment (in these Regulations referred to as “the patients' guide”) which shall include—

- (a) a summary of the statement of purpose;
- (b) the terms and conditions in respect of services to be provided for patients, including as to the amount and method of payment of charges by patients for all aspects of their treatment;
- (c) a standard form of contract for the provision of services and facilities by the registered provider to patients;
- (d) a summary of the complaints procedure established under regulation 22;
- (e) a summary of the results of the most recent consultation conducted in accordance with regulation 16(3);
- (f) the address and telephone number of the appropriate office of the National Assembly; and
- (g) the most recent inspection report prepared by the National Assembly or information as to how a copy of that report may be obtained.

(2) The registered person shall provide a copy of the first patients' guide to the appropriate office of the National Assembly, and shall ensure that a copy of the current version of the patient's guide is provided to every patient and any person acting on behalf of a patient.

Review of statement of purpose and patients' guide

7. The registered person shall—

- (a) keep under review and, where appropriate, revise the statement of purpose and the content of the patients' guide; and
- (b) whenever practicable notify the appropriate office of the National Assembly of any such revision at least 28 days before it is to take effect.

Policies and procedures

8.—(1) The registered person shall prepare and implement written statements of the policies to be applied and the procedures to be followed in or for the purposes of an establishment in relation to—

- (a) the arrangements for admission or acceptance of patients, their transfer to a hospital, including to a health service hospital, where required and, in the case of an establishment which admits in-patients, their discharge;
 - (b) the arrangements for assessment, diagnosis and treatment of patients;
 - (c) ensuring that the establishment premises are at all times fit for the purpose for which they are used;
 - (d) monitoring the quality and suitability of facilities and equipment;
 - (e) identifying, assessing and managing risks associated with the operation of the establishment to employees, patients and visitors;
 - (f) the creation, management, handling and storage of records and other information;
 - (g) the provision of information to patients and others;
 - (h) the recruitment, induction and retention of employees and their employment conditions;
 - (i) the granting, and withdrawal, of practising privileges to medical practitioners in establishments where such privileges are granted; and
 - (j) ensuring that, where research is carried out in an establishment, it is carried out with the consent of any patient or patients involved, is appropriate for the establishment concerned and is conducted in accordance with up-to-date and authoritative published guidance on the conduct of research projects.
- (2) The registered person shall prepare and implement written statements of policies to be applied and procedures to be followed in or for the purposes of an establishment which ensure that—
- (a) the competence of each patient to consent to treatment is assessed;
 - (b) in the case of a competent patient, properly informed written consent to treatment is obtained before any proposed treatment is administered;
 - (c) in the case of a patient who is not competent, the patient is, so far as practicable, consulted before any proposed treatment is administered; and
 - (d) information about a patient’s health and treatment is disclosed only to those persons who need to be aware of that information in order to treat the patient effectively or minimise any risk of the patient harming himself or herself or another person, or for the purpose of the proper administration of the establishment.
- (3) The registered person shall review the operation of each policy and procedure implemented under—
- (a) this regulation;
 - (b) regulation 22; and
 - (c) in so far as they apply to the registered person regulations 34, 40 (10), 44 and 45;
- at intervals of not more than three years and shall, where appropriate, prepare and implement revised policies and procedures.
- (4) The registered person shall make a copy of all written statements prepared in accordance with this regulation available for inspection by the National Assembly.