WELSH STATUTORY INSTRUMENTS

2011 No. 734

The Independent Health Care (Wales) Regulations 2011

PART 1

General

Title, commencement and application

1.—(1) The title of these Regulations is the Independent Health Care (Wales) Regulations 2011 and they come into force on 5 April 2011.

(2) These Regulations apply in relation to Wales only.

Interpretation

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

"the 2005 Act" ("*Deddf 2005*") means the Mental Capacity Act 2005(**1**);

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

"agency" ("*asiantaeth*") means an independent medical agency;

"appropriate office of the registration authority" ("s*wyddfa briodol yr awdurdod cofrestru*") means in relation to an establishment or agency—

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

(b) in any other case, any office of the registration authority;

"approved places" ("*lleoedd cymeradwy*") means, in relation to an independent hospital, a bed which is available in accordance with any condition placed upon the registration of any person in respect of the independent hospital, for the use by a patient at night;

"dentist" ("*deintydd*") means a person registered in the dentists register under the Dentists Act 1984(**2**);

"establishment" ("*sefydliad*") means an independent hospital or an independent clinic;

"Financial Services Authority" ("*Awdurdod Gwasanaethau Ariannol*") means the body established under section 1 of the Financial Services and Markets Act 2000(**3**);

"general practitioner" ("*ymarferydd cyffredinol*") means a medical practitioner who provides primary medical services pursuant to sections 41, 42 and 50 of the NHS Act;

"health care professional" ("*proffesiynolyn 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 and "health care profession" must be construed accordingly;

(**1**) 2005 c. 9.
(**2**) 1984 c. 24.
(**3**) 2000 c. 8.
(**4**) 1999 c. 8.

"health care record" ("*cofnod gofal iechyd*") means any record which—

(a) consists of information relating to the physical or mental health or condition of an individual, and

(b) has been made by or on behalf of a health professional in connection with the care of that individual;

"insurance provider" ("*darparwr yswiriant*") means—

(a) a person regulated by the Financial Services Authority who sells insurance, or underwrites the risk of such insurance, or

(b) the agent of such a person;

"medical device" ("*dyfais feddygol*") has the same meaning as in the Medical Devices Regulations 2002(**5**);

"medical practitioner" ("*ymarferydd meddygol*") means a registered medical practitioner;

"midwife" ("*bydwraig*") means a registered midwife who has notified her intention to practise to the local supervisory authority in accordance with any rules made under article 42 of the Nursing and Midwifery Order 2001(**6**);

"the NHS Act" ("*Deddf y GIG*") means the National Health Service (Wales) Act 2006(**7**);

"organisation" ("*corff*") means a body corporate;

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

"patients' guide" ("*arweiniad y cleifion*") means the guide compiled in accordance with regulation 7;

"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 or agency, means a person who is registered under Part II of the Act as the manager of the establishment or agency;

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

"registered provider" ("*darparwr cofrestredig*"), in relation to an establishment or agency, means a person who is registered under Part II of the Act as the person carrying on the establishment or agency;

"responsible individual" ("*unigolyn cyfrifol*") is to be construed in accordance with regulation 10;

"specialist medical register" ("*cofrestr feddygol arbenigol*") means the register of specialist medical practitioners kept by the General Medical Council in accordance with section 34D of the Medical Act 1983(**8**);

"statement of purpose" ("*datganiad o ddiben*") means the written statement compiled in accordance with regulation 6;

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

(**5**) S.I.2002/618.
(**6**) S.I. 2002/253.
(**7**) 2006 c. 42.
(**8**) 1983 c. 54. This section was inserted by S.I.2010/234 (article 4, Schedule 1, paragraph 10).

(2) The registration authority may specify an office controlled by it as the appropriate office in relation to establishments and agencies 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;

(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 is to be construed accordingly.

Meaning of "independent hospital"

3.—(1) Subject to paragraph (2), for the purposes of section 2(7)(f) of the Act, treatment using any of the following techniques or technology are prescribed—

(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)(**9**);

(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) circumcision of male children by a health care professional, including for the purpose of religious observance;

(d) haemodialysis or peritoneal dialysis;

(e) endoscopy;

(f) hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a patient who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the direct supervision or direction of a medical practitioner and where the primary use of that chamber is otherwise than for the treatment of workers in connection with the work which they perform; and

(g) *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(**10**).

(2) "Listed services" do 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—

(**9**) Copies of BS EN 60825-1 may be obtained from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.
(**10**) 1990 c. 37.

(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 or palliative care but which has no approved places;

(b) an establishment which is a service hospital within the meaning of Schedule 12 of the Armed Forces Act 2006(**11**);

(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(**12**);

(d) 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 medical services within the meaning of Part IV of the NHS Act; and such an establishment will not be an independent hospital as the result of the provision of listed services to a patient or patients by such a general practitioner or practitioners;

(e) the private residence of a patient or patients in which treatment is provided to such patient or patients but to no-one else;

(f) sports grounds and gymnasia where health care professionals provide treatment to persons taking part in sporting activities and events; and

(g) a surgery or consulting room, (which is not part of a hospital), in which a medical practitioner provides medical services only under arrangements made on behalf of the patients by—

(i) their employer,

(ii) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983(**13**), or

(iii) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity;

(h) an establishment which is a hospital by virtue of section 2(7)(a) of the Act solely because it provides—

(i) nail surgery,

(ii) nail bed procedures, or

(iii) curettage, cautery or the cryocautery of warts, verrucae or other skin lesions,

on any areas of the foot and uses local anaesthesia during these procedures; and

(i) an establishment which is a hospital by virtue of section 2(7)(a) of the Act solely because a medical practitioner provides curettage, cautery or the cryocautery of warts, verrucae or other skin lesions and uses local anaesthesia during that procedure.

(4) In this regulation "local anaesthesia" ("*anesthesia lleol*") means any anaesthesia other than general, spinal or epidural anaesthesia, and also excludes the administration of a regional nerve block.

(5) The definition of "listed services" in subsection (7) of section 2 of the Act has effect as if in paragraph (a) of that definition the words "intravenously administered" were inserted after "or".

(**11**) 2006 c. 52. *See* paragraph 12 of the Schedule.
(**12**) 1952 c. 52.
(**13**) 1983 c. 20.

Meaning of "independent clinic"

4.—(1) For the purposes of the Act a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the NHS Act in that establishment provides medical services of any kind (including psychiatric treatment) otherwise than under arrangements made on behalf of the patients by their employer, is prescribed as an independent clinic.

(2) Paragraph (1) does not apply if the medical services are provided only under arrangements made on behalf of the patients by—

(i) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983, or

(ii) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis of treatment of physical or mental illness, disability or infirmity.

(3) 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 will be regarded as carrying on a separate independent clinic unless they are in practice together.

Exception of undertaking from the definition of independent medical agency

5. For the purposes of the Act, any undertaking which consists of the provision of medical services by a medical practitioner only under arrangements made on behalf of the patients by—

(a) their employer;

(b) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983; or

(c) an insurance company with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity,

is excepted from being an agency.

Statement of purpose

6.—(1) The registered person must compile in relation to the establishment or agency a statement on paper (in these Regulations referred to as "the statement of purpose") which must consist of a statement as to the matters listed in Schedule 1.

(2) The registered person must provide a copy of the statement of purpose to the appropriate office of the registration authority and must 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 must ensure that the establishment or agency is conducted in a manner which is consistent with its statement of purpose.

(4) Nothing in paragraph (3), regulation 15(1) or 26(1) and (2) requires or authorises 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

7.—(1) The registered person must produce a written guide to the establishment or agency (in these Regulations referred to as "the patients' guide") which must 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 24;

(e) where available, a summary of the views of patients and others obtained in accordance with regulation 19(2)(e);

(f) the address and telephone number of the appropriate office of the registration authority; and

(g) the most recent inspection report prepared by the registration authority or information as to how a copy of that report may be obtained.

(2) The registered person must provide a copy of the first patients' guide to the appropriate office of the registration authority, and must 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

8. The registered person must—

(a) keep under review and, where appropriate, revise the statement of purpose and the content of the patients' guide; and

(b) notify the appropriate office of the registration authority of any such revision at least 28 days before it is to take effect.

Policies and procedures

9.—(1) The registered person must 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 each of the matters specified below and for the purposes of an agency each of the matters specified in sub-paragraphs (b), (d), (f), (g), (h), (i), (m) and (n)—

(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 has approved places, 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, including maintenance of such equipment;

(e) identifying, assessing and managing risks associated with the operation of the establishment to employees, patients, visitors and those working in or for the purposes of the establishment;

(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) ensuring safe recruitment of staff including undertaking checks appropriate to the work that staff are to undertake;

(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;

(k) the arrangements for ensuring the health and safety of staff and patients;

(l) the safe keeping of patient property and possessions in an establishment in cases where such property or possessions have been removed from the patient as they may put the patient at risk of harm;

(m) the ordering, recording, administration and supply of medicines to patients;

(n) the arrangements relating to infection control including hand hygiene, safe handling and disposal of clinical waste, housekeeping and cleaning regimes and relevant training and advice;

(o) the arrangements for clinical audit; and

(p) the granting, and withdrawal, of practising privileges to medical practitioners in establishments where such privileges are or may be granted.

(2) The registered person must prepare and implement a written policy setting out—

(a) how disturbed behaviour exhibited by a patient is to be managed;

(b) permitted measures of restraint and the circumstances in which they may be used;

(c) requirements for employees to report serious incidents of violence or self harm, including guidance as to how those incidents should be classified; and

(d) the procedure for review of such incidents and determination of the action which is to be taken subsequently.

(3) The written statements and policies referred to in paragraphs (1) and (2) must be prepared having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients.

(4) The registered person must prepare and implement written statements of policies to be applied and procedures to be followed in or for the purposes of an establishment or agency which ensure that—

(a) the capacity of each patient to consent to treatment is assessed;

(b) in the case of a patient who has capacity, properly informed, and where appropriate, written consent to treatment is obtained before any proposed treatment is administered;

(c) in the case of a patient who lacks capacity the requirements of the 2005 Act are complied with before any treatment proposed for him is administered;

(d) national and best practice guidance is taken into account; and

(e) 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.

(5) The registered person must review the operation of policies and procedures implemented under—

(a) this regulation;

(b) regulation 24; and

(c) in so far as they apply to the registered person, regulations 38, 44 (7) and 48;

at intervals of not more than three years and, where appropriate, revise and implement those policies and procedures.

(6) The registered person must retain copies of all policies and procedures referred in this regulation, including previous versions of policies and procedures that have been revised in accordance with paragraph (5), for a period of not less than three years from the date of creation or revision of the policy or procedure.

(7) The registered person must make a copy of all written statements prepared in accordance with this regulation available for inspection by the registration authority.