
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” (“*swyddfa 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 gymnasias 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.

PART II

Registered Persons

Fitness of registered provider

10.—(1) A person must not carry on an establishment or agency unless the person is fit to do so.

(2) A person is not fit to carry on an establishment or agency unless the person—

(a) is an individual who satisfies the requirements set out in paragraph (3); or

(b) is an organisation and—

(i) the organisation has given notice to the appropriate office of the registration authority of the name, address and position in the organisation of an individual (in these Regulations referred to as “the responsible individual”) who is a director, manager, secretary or other officer of the organisation and is responsible for supervising the management of the establishment or agency; and

(ii) that individual satisfies the requirements set out in paragraph (3).

(3) The requirements are that—

(a) the individual is of suitable integrity and good character to carry on, or, as the case may be, be responsible for the supervision of the management of, the establishment or agency;

(b) the individual is physically and mentally fit to carry on, or, as the case may be, be responsible for the supervision of the management of, the establishment or agency; and

(c) full and satisfactory information or documentation, as the case may be, is available in relation to the individual in respect of each of the matters specified in paragraphs 1, 2 and 4 to 8 of Schedule 2.

(4) A person is not fit to carry on an establishment or agency if—

(a) the person has been adjudged bankrupt or sequestration of the person’s estate has been awarded and (in either case) the person has not been discharged and the bankruptcy order has not been annulled or rescinded or a moratorium period under a debt relief order applies in relation to the person; or

(b) the person has made a composition or arrangement with the person’s creditors and has not been discharged in respect of it.

Appointment of manager

11.—(1) The registered provider must appoint an individual to manage the establishment or agency if—

(a) there is no registered manager in respect of the establishment or agency; and

(b) the registered provider—

- (i) is an organisation;
- (ii) is not a fit person to manage an establishment or agency; or
- (iii) is not, or does not intend to be in full-time day to day charge of the establishment or agency.

(2) If the registered provider appoints a person to manage the establishment or agency, the registered provider must forthwith give notice to the appropriate office of the registration authority of—

- (a) the name of the person so appointed; and
- (b) the date on which the appointment is to take effect.

(3) If the registered provider is to manage the establishment or agency he or she must forthwith give notice to the appropriate office of the registration authority of the date on which such management is to begin.

Fitness of manager

12.—(1) A person must not manage an establishment or agency unless the person is fit to do so.

(2) A person is not fit to manage an establishment or agency unless—

- (a) the person is of suitable integrity and good character to manage the establishment or agency;
- (b) having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients—
 - (i) the person has the qualifications, skills and experience necessary to manage the establishment or agency; and
 - (ii) the person is physically and mentally fit to do so; and
- (c) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in paragraphs 1, 2 and 4 to 8 of Schedule 2.

(3) Where a person manages more than one establishment or agency he or she must spend sufficient time at each establishment or agency to ensure that the establishment or agency is managed effectively.

Registered person-general requirements

13.—(1) The registered provider and the registered manager must, having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients, carry on or manage the establishment or agency, as the case may be, with sufficient care, competence and skill.

(2) If the registered provider is—

- (a) an individual, he or she must undertake; or
- (b) an organisation, it must ensure that the responsible individual undertakes,

from time to time such training as is appropriate to ensure that he or she has the skills necessary for carrying on the establishment or agency.

(3) Any individual managing the establishment or agency must undertake from time to time such training as is appropriate to ensure that he or she has the skills necessary for managing the establishment or agency.

Notification of offences

14.—(1) Where the registered person or the responsible individual is convicted of any criminal offence, whether in Wales or elsewhere, the person convicted must forthwith give notice in writing to the appropriate office of the registration authority of—

- (a) the date and place of the conviction;
- (b) the offence of which the person was convicted; and
- (c) the penalty imposed on the person in respect of the offence.

(2) Where the registered person or the responsible individual is charged with any offence in respect of which an order may be made under Part II of the Criminal Justice and Court Services Act 2000 (Protection of Children)(14) the registered person or responsible individual must forthwith give notice in writing to the appropriate office of the registration authority of the offence charged and the date and place of the charge.

PART III

Conduct of Health Care Establishments and Agencies

Chapter 1

Quality of Service Provision

Quality of treatment and other service provision

15.—(1) Subject to regulation 6(4), the registered person must provide any treatments and other services to patients in accordance with the statement of purpose, and must ensure that any treatments and other services provided to each patient—

- (a) meet the patient's individual needs;
- (b) ensure the welfare and safety of the patient;
- (c) are evidence based; and
- (d) are (where necessary) provided by means of appropriate equipment.

(2) The registered person must ensure that all equipment used in or for the purposes of the establishment or for the purposes of the agency is safe and in good condition and suitable for the purpose it is to be used for.

(3) Where reusable medical devices are used in an establishment or for the purposes of an agency, the registered person must ensure that appropriate procedures are implemented in relation to cleaning, disinfection, inspection, packaging, sterilisation, transportation and storage of such devices.

(4) The procedures implemented in accordance with paragraph (3) must be such as to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.

(5) The registered person must protect patients against the risks associated with the unsafe use and management of medicines, by means of—

- (a) the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used in or for the purposes of the establishment or agency; and
- (b) having regard to any guidance issued by the registration authority or appropriate expert body in relation to the safe handling and use of medicines.

(6) The registered person must ensure that where blood and blood products are used a monitoring process for the safety of blood transfusion (haemovigilance) is in place.

(7) The registered person must, so far as reasonably practicable, ensure that—

- (a) patients; and
- (b) others who may be at risk of exposure to a health care associated infection arising from working in or for the purposes of an establishment or agency,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (8).

(8) The means referred to in paragraph (7) are—

- (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
- (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
- (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
 - (i) premises occupied for the purpose of carrying on the establishment or agency;
 - (ii) equipment and reusable medical devices used for the purpose of carrying on the establishment or agency; and
 - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

(9) If an establishment provides food and drink for patients as a component of the patients' care, the registered person must ensure that—

- (a) Patients' nutritional and hydration needs are assessed and documented on admission and at regular intervals thereafter;
- (b) Food and hydration is provided that meets individual patient nutritional and hydration needs.

(10) The registered person must take account of any advice bulletins relating to the type of treatment the establishment or agency provides and to patient safety information published by appropriate regulatory, professional or appropriate statutory expert bodies.

Safeguarding patients from abuse

16.—(1) The registered person must make suitable arrangements to ensure that patients are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the establishment or for the purposes of an agency, the registered person must have suitable arrangements in place to protect patients against the risk of such control or restraint being—

- (a) unlawful; or
- (b) otherwise excessive.

(3) The registered person must have regard to any guidance issued by the registration authority or appropriate expert body, in relation to—

- (a) the protection of children and vulnerable adults generally; and
- (b) in particular, the appropriate use of methods of control or restraint.

- (4) For the purposes of paragraph (1), “abuse” (“*cam-drin*”), in relation to a patient, means—
- (a) sexual abuse;
 - (b) physical or psychological ill-treatment;
 - (c) theft, misuse or misappropriation of money or property; or
 - (d) neglect and acts of omission which cause harm or place at risk of harm.

Capacity of patients

17.—(1) The registered person must, so far as is practicable, and, where the patient lacks capacity, in accordance with the principles of the 2005 Act enable each patient to make decisions about matters affecting the way in which the patient is cared for and his or her welfare.

(2) The registered person must ensure that patients are enabled to control their own money, except where a patient does not wish, or lacks capacity to do so, in which case the registered person must ensure that patient monies are properly held and recorded and that receipts are issued as appropriate.

(3) The registered person must so far as practicable, and where patients lack capacity, in accordance with the principles of the 2005 Act ascertain and take into account the wishes and feelings of all patients in determining the manner in which they are cared for and services are provided to them.

Privacy, dignity and relationships

18.—(1) The registered person must make suitable arrangements to ensure that the establishment or agency is conducted—

- (a) in a manner which respects the privacy and dignity of patients; and
- (b) with due regard to the sex, religious persuasion, racial origin, sexual orientation, cultural and linguistic background and any disability of patients.

(2) The registered provider and the registered manager (if any) must each take all reasonable steps to ensure that the establishment or agency is conducted on the basis of good personal and professional relationships—

- (a) between each other; and
- (b) between each of them and the patients and staff.

Assessing and monitoring the quality of service provision including annual returns

19.—(1) The registered person must protect patients, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the establishment or agency against the requirements set out in these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of patients and others.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
 - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by patients, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 24;

- (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the establishment or agency;
- (iii) the information contained in the records referred to in regulation 23;
- (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a));
- (v) reports prepared by the registration authority from time to time pursuant to section 32(5) of the Act in relation to the establishment or agency;
- (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
 - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a patient; and
 - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;
- (d) establish mechanisms for ensuring that decisions in relation to the provision of care and treatment for patients are taken at the appropriate level and by an appropriate person; and
- (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of patients, persons acting on their behalf, persons who are employed for the purposes of the establishment or agency and any medical practitioner with practising privileges, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to patients.

(3) The registered person must send to the appropriate office of the registration authority, when requested to do so, a written annual assessment (referred to as the “annual return”) setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with in relation to the establishment or agency, together with any plans that the registered person has for improving the standard of the services provided to patients with a view to ensuring their health and welfare.

(4) The registered person must take reasonable steps to ensure that the annual return is not misleading or inaccurate.

(5) The registered person must supply the annual return to the appropriate office of the registration authority within 28 days of receiving a request under paragraph (3).

Staffing

20.—(1) The registered person must, having regard to the nature of the establishment or agency, the statement of purpose and the number and needs of patients—

- (a) ensure that at all times suitably qualified, skilled and experienced persons are working in or for the purposes of the establishment or as the case may be, for the purposes of the agency, in such numbers as are appropriate for the health and welfare of the patients;
- (b) ensure that the employment of any persons on a temporary basis in or for the purposes of the establishment or for the purposes of the agency will not prevent patients from receiving such continuity of care as is reasonable to meet their needs.

(2) The registered person must ensure that each person employed in or for the purposes of the establishment, or for the purposes of the agency—

- (a) receives appropriate training, supervision and appraisal;
- (b) is enabled from time to time to obtain further qualifications appropriate to the work the person performs; and

(c) is provided with a job description outlining the person's responsibilities.

(3) The registered person must ensure that each person employed in or for the purposes of the establishment or for the purposes of the agency and any medical practitioner with practising privileges, receives regular and appropriate appraisal and must take such steps as may be necessary to address any aspect of—

- (a) a health care professional's clinical practice; or
- (b) the performance of a member of staff who is not a health care professional,

which is found to be unsatisfactory.

(4) The registered person must take reasonable steps to ensure that any persons working in or for the purposes of an establishment or for the purposes of an agency who are not employed by the registered person and to whom paragraph (2) does not apply, are appropriately supervised to ensure patients' health and welfare is not compromised, while carrying out their duties.

Fitness of workers

21.—(1) Subject to paragraph (4) the registered person must not—

- (a) employ under a contract of employment a person to work in or for the purposes of the establishment or for the purposes of the agency unless that person is fit to do so;
- (b) allow a volunteer to work in or for the purposes of the establishment or for the purposes of the agency unless that person is fit to do so;
- (c) allow any other person (including a medical practitioner seeking the grant of practising privileges) to work in or for the establishment or for the purposes of the agency in a position in which he or she may in the course of his or her duties have regular contact with a patient unless that person is fit to work in or for the establishment or for the purposes of the agency.

(2) For the purposes of paragraph (1) a person is not fit to work in or for the purposes of an establishment or for the purposes of an agency unless—

- (a) the person is of suitable integrity and good character for the work which the person is to perform;
- (b) the person has the qualifications, skills and experience which are necessary for that work;
- (c) the person is physically and mentally fit for that work; and
- (d) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.

(3) The certificate referred to in paragraph 3 of Schedule 2 must be applied for by, or on behalf of the registered person, for the purpose of assessing the suitability of a person for the post referred to in paragraph (1).

(4) The registered person must ensure that—

- (a) any offer of employment to, or other arrangement about working in or for the purposes of the establishment or for the purposes of the agency made with or in respect of a person described in paragraph (1) is subject to paragraph (2)(d) being complied with in relation to that person; and
- (b) unless paragraph (5) applies, no such person starts work in or for the purposes of the establishment or for the purposes of the agency until such time as paragraph (2)(d) has been complied with in relation to that person.

(5) Where the following conditions apply, the registered person may permit a person other than a health care professional to start work in or for the purposes of the establishment or for the purposes of an agency notwithstanding paragraphs (1) and (4)(b)—

- (a) the registered person has taken all reasonable steps to obtain full information in respect of each of the matters listed in paragraphs 1 and 3 to 8 of Schedule 2 in respect of that person, but the enquiries in relation to any of the matters listed in paragraphs 4 to 8 of Schedule 2 are incomplete;
 - (b) full and satisfactory information in relation to that person has been obtained in respect of the matters specified in paragraphs 1 and 3 of Schedule 2;
 - (c) in the reasonable opinion of the registered person the circumstances are exceptional; and
 - (d) pending receipt of, and being satisfied with regard to, any outstanding information, the registered person ensures that the person is appropriately supervised while carrying out his or her duties.
- (6) The registered person must ensure that any person working in or for the purposes of the establishment or agency who does not fall within paragraph (1) is appropriately supervised at all times when they are in contact with patients.

Guidance for health care professionals

22. The registered person must ensure that any code of ethics or professional practice prepared by a body which is responsible for regulation of members of a health care profession is made available in the establishment or agency to members of the health care profession in question.

Records

- 23.—**(1) The registered person must ensure that except in cases to which regulation 43(5) applies—
- (a) a comprehensive health care record which may be in paper or electronic form is maintained in relation to each patient, which includes—
 - (i) a contemporaneous note of all treatment provided to the patient;
 - (ii) the patient’s medical history and all other notes prepared by a health care professional about the patient’s case; and
 - (b) the record is retained for a period which is not less than that specified in Part I of Schedule 3 in relation to the type of patient in question or, where more than one such period could apply, the longest of them.
- (2) The registered person must ensure that—
- (a) the health care record for a person who is currently a patient is kept in a secure place in the establishment or agency premises; and
 - (b) the health care record for a person who is not currently a patient is stored securely (whether in the establishment or agency or elsewhere) and that it can be located if required.
- (3) In addition to the health care records maintained in accordance with paragraph (1), the registered person must ensure that the records, which may be in paper or electronic form, specified in Part II of Schedule 3 are maintained and that they are—
- (a) kept up to date;
 - (b) at all times available for inspection in the establishment or agency by any person authorised by the registration authority to enter and inspect the establishment or agency; and
 - (c) retained for a period of not less than three years beginning on the date of the last entry.
- (4) Where an establishment or agency closes the registered person must ensure that the records maintained in accordance with paragraphs (1) and (3) are kept securely elsewhere and must make them available for inspection by the registration authority at its request.

Complaints

24.—(1) The registered person must establish a procedure (in these Regulations referred to as “the complaints procedure”) for considering complaints made to the registered person by a patient or a person acting on behalf of a patient.

(2) The registered person must ensure that any complaint made under the complaints procedure is fully investigated.

(3) The registered person must supply a written copy of the complaints procedure upon request, to—

- (a) every patient;
- (b) any person acting on behalf of a patient; and
- (c) any person who is considering whether to become a patient.

(4) The written copy of the complaints procedure must include—

- (a) the name, address and telephone number of the appropriate office of the registration authority; and
- (b) the procedure (if any) which has been notified by the registration authority to the registered person for making complaints to the registration authority relating to the establishment or agency.

(5) The registered person must maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence including whether any action is necessary to improve the quality of treatment or services and the requirements of regulation 23(3) (b) and (c) will apply to that record.

(6) The registered person must supply to the registration authority at its request copies of records maintained under paragraph (5).

Research

25.—(1) The registered person must ensure that—

- (a) before any research involving patients, information about patients, or human tissue is undertaken in or for the purposes of an establishment, a research proposal is prepared and approval is obtained from the appropriate Research Ethics Committee; and
- (b) all such research projects include adequate safeguards for patients and employees.

(2) For the purposes of paragraph (1)(a), “the appropriate Research Ethics Committee” (“*y Pwyllgor Moeseg Ymchwil priodol*”) means a research ethics committee established in accordance with guidance issued from time to time by the registration authority or appropriate expert body.

Chapter 2

Premises

Fitness of premises

26.—(1) The registered person must not use premises for the purposes of an establishment or agency unless those premises are in a location and of a physical design and layout, which are suitable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person must ensure that—

- (a) the premises provide a clean, safe and secure environment in accordance with current legislation and best practice;

- (b) the premises are of sound construction and kept in a good state of repair externally and internally;
 - (c) the size and layout of the establishment is suitable for the purposes for which they are used and are suitably equipped and furnished;
 - (d) if surgical procedures are undertaken, life support systems are used, or obstetric services and, in connection with childbirth, medical services, are provided in the establishment, such electrical supply is provided during the interruption of public supply as is needed to safeguard the lives of the patients.
- (3) The registered person must provide for employees and medical practitioners with practising privileges —
- (a) suitable facilities and accommodation, other than sleeping accommodation, including—
 - (i) facilities for the purpose of changing; and
 - (ii) storage facilities; and
 - (b) where the provision of such accommodation is needed by employees in connection with their work, sleeping accommodation.
- (4) Subject to paragraph 5 the registered person must—
- (a) take adequate precautions against the risk of fire, including the provision and maintenance of adequate fire prevention and detection equipment;
 - (b) provide adequate means of escape in the event of a fire;
 - (c) make arrangements for persons employed in the establishment and medical practitioners to whom practising privileges have been granted to receive suitable training in fire prevention;
 - (d) ensure, by means of fire drills and practices at suitable intervals, that the persons employed in the establishment and, so far as practicable, patients and medical practitioners to whom practising privileges have been granted, are aware of the procedure to be followed in case of fire;
 - (e) review fire precautions, the suitability of fire equipment and the procedure to be followed in case of fire at intervals not exceeding twelve months; and
 - (f) produce a written fire safety risk assessment.
- (5) Where the Regulatory Reform (Fire Safety) Order 2005(15) applies to the premises—
- (a) paragraph (4) does not apply; and
 - (b) the registered person must ensure that the requirements of that Order and any regulations made under it, except for article 23 (duties of employees), are complied with in respect of those premises.

Fitness of premises – learning disability

27.—(1) Subject to regulation 53—

- (a) the registered person must ensure that an independent hospital that provides, or intends to provide, overnight accommodation—
 - (i) for a consecutive period of 12 months or more for patients diagnosed with a learning disability together with patients with a mental illness; or
 - (ii) for a consecutive period of 12 months or more to a patient diagnosed with both a learning disability and mental illness,

must not exceed 15 approved places.

- (b) the registered person must ensure that an independent hospital that provides, or intends to provide, overnight accommodation to a patient diagnosed with learning disabilities who does not fall within sub-paragraph (1)(a), for a consecutive period of 12 months or more, must not exceed 10 approved places.

(2) The registered person must ensure that, where reasonably practicable, the approved places referred to in paragraph (1) are provided in two or more units of the independent hospital.

Chapter 3

Management

Visits by registered provider to establishments

28.—(1) Where the registered provider is an individual who does not manage the establishment, that individual must visit the establishment premises in accordance with this regulation.

(2) Where the registered provider is an organisation, the establishment must be visited in accordance with this regulation by—

- (a) the responsible individual;
- (b) another of the directors or other persons responsible for the management of the organisation who is suitable to visit the establishment; or
- (c) an employee of the organisation who has appropriate qualifications, skills and experience for the purpose and who is not directly concerned with the conduct of the establishment.

(3) Visits under paragraph (1) or (2) must take place at least every six months and may be unannounced.

(4) The person carrying out the visit must—

- (a) interview, with their consent and in private (if necessary, by telephone), such of the patients and their representatives and such employees as appear to be necessary in order to form an opinion of the standard of treatment and other services provided in or for the purposes of the establishment;
- (b) inspect the premises and records of any complaints; and
- (c) prepare a written report on the conduct of the establishment.

(5) The registered provider must supply a copy of the report required to be made under paragraph (4)(c) to—

- (a) the registration authority;
- (b) the registered manager; and
- (c) in the case of a visit under paragraph (2), to each of the directors or other persons responsible for the management of the organisation.

Financial position

29.—(1) The registered provider must carry on the establishment or agency in such manner as is likely to ensure that the establishment or agency will be financially viable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person must, if the registration authority so requests, provide it with such information and documents as it may require for the purpose of considering the financial viability of the establishment or agency, including—

- (a) the annual accounts of the establishment or agency, certified by an accountant; or

- (b) the annual accounts of the organisation which is the registered provider of the establishment or agency, certified by an accountant, together with accounts relating to the establishment or agency itself.
- (3) The registered person must also provide the registration authority with such other information as it may require in order to consider the financial viability of the establishment or agency, including—
 - (a) a reference from a bank expressing an opinion as to the registered provider’s financial standing;
 - (b) information as to the financing and financial resources of the establishment or agency;
 - (c) where the registered provider is a company, information as to any of its associated companies; and
 - (d) a certificate of insurance for the registered provider in respect of liability which may be incurred by the provider in relation to the establishment or agency in respect of death, injury, public liability, damage or other loss.
- (4) In this regulation, one company is associated with another if one of them has control of the other, or both are under the control of the same person.

Chapter 4

Notices to be given to the registration authority

Notification of death or unauthorised absence of a patient who is detained or liable to be detained under the Mental Health Act 1983

30.—(1) The registered person must notify the registration authority without delay of the death or unauthorised absence of a patient who is liable to be detained by the registered person—

- (a) under the Mental Health Act 1983 (“the 1983 Act”); or
 - (b) pursuant to an order or direction made under another enactment (which applies in relation to Wales), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.
- (2) In this regulation—
- (a) References to persons “liable to be detained” (“*agored i’w caethiwo*”) include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act, but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42, 73 or 74 of the 1983 Act;
 - (b) “community patient” (“*claf cymunedol*”) has the same meaning as in section 17A of the 1983 Act;
 - (c) “hospital” (“*ysbyty*”) means a hospital within the meaning of Part 2 of that Act; and
 - (d) “unauthorised absence” (“*absenoldeb diawdurdod*”) means an unauthorised absence from a hospital.

Notification of events

31.—(1) The registered person must give notice to the appropriate office of the registration authority of—

- (a) the death of a patient—
 - (i) in an establishment;
 - (ii) during treatment provided in or for the purposes of an establishment or for the purposes of an agency; or

- (iii) as a consequence of treatment provided in or for the purposes of an establishment or for the purposes of an agency;
and the date, time, cause (where known) and circumstances of the patient’s death;
- (b) any serious injury to a patient;
- (c) the outbreak in an establishment of any infectious disease, which in the opinion of any medical practitioner employed in the establishment is sufficiently serious to be so notified;
- (d) any allegation of misconduct resulting in actual or potential harm to a patient by the registered person, any person employed in or for the purposes of the establishment or for the purposes of an agency, or any medical practitioner with practising privileges;
- (e) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;
- (f) any application made to a court in relation to depriving a patient of their liberty.

(2) For the purposes of this regulation, references to a supervisory body are to a supervisory body as defined in Schedule A1 to the 2005 Act⁽¹⁶⁾ and “standard authorisation” (“*awdurdodiad safonol*”) has the meaning given under Part 4 of Schedule A1 to the 2005 Act.

(3) Notice under paragraph (1) must be given within the period of 24 hours beginning with the event in question and, if given orally, must be confirmed in writing within 72 hours of the oral notification.

- (4) If the registered person—
 - (a) receives information concerning the death of a patient who has undergone termination of a pregnancy in an independent hospital during the period of 12 months ending on the date on which the information is received; and
 - (b) has reason to believe that the patient’s death may be associated with the termination, the registered person must give notice in writing to the appropriate office of the registration authority of that information, within the period of 14 days beginning on the day on which the information is received.

Notice of absence of registered person

32.—(1) Where—

- (a) a registered provider who manages the establishment or agency; or
- (b) a registered manager,

proposes to be absent from the establishment or agency for a continuous period of 28 days or more, the registered person must give notice in writing to the appropriate office of the registration authority of the absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than one month before the proposed absence commences or within such shorter period as may be agreed with the registration authority and the notice must specify with respect to the absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for running the establishment or agency;
- (d) the name, address and qualifications of the person who will be responsible for the establishment or agency during that absence; and

⁽¹⁶⁾ See Schedule A1, part 13.

- (e) the arrangements that have been or are proposed to be made for appointing another person to manage the establishment or agency during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence arises as a result of an emergency, the registered person must give notice of the absence within one week of the emergency's occurrence specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(4) Where—

- (a) a registered provider who manages the establishment or agency; or
- (b) a registered manager,

has been absent from the establishment or agency for a continuous period of 28 days or more, and the appropriate office of the registration authority has not been given notice of the absence, the registered person must, without delay, give notice in writing to that office, specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(5) The registered person must notify the appropriate office of the registration authority of the return to work of a person mentioned in sub-paragraph (a) or (b) of paragraph (4) not later than 7 days after the date of that person's return.

Notice of changes

33.—(1) The registered person must give notice in writing to the appropriate office of the registration authority as soon as it is practicable to do so if any of the following events take place or are proposed to take place—

- (a) a person other than the registered person carries on or manages the establishment or agency;
- (b) a person ceases to carry on or manage the establishment or agency;
- (c) where the registered person is an individual, he or she changes his or her name;
- (d) where the registered provider is an organisation—
 - (i) the name or address of the organisation is changed;
 - (ii) there is any change of director, manager, secretary or other similar officer of the organisation;
- (e) the responsible individual changes his or her name;
- (f) there is any change in the identity of the responsible individual;
- (g) where the registered provider is an individual, a trustee in bankruptcy is appointed or a composition or arrangement is made with creditors;
- (h) where the registered provider is a company or partnership, a receiver, manager, liquidator or provisional liquidator is appointed; or
- (i) the premises of the establishment are significantly altered or extended, or additional premises are acquired which are intended to be used for the purposes of the establishment.

Appointment of liquidators etc

34.—(1) Any person to whom paragraph (2) applies must—

- (a) forthwith notify the appropriate office of the registration authority of the person's appointment indicating the reasons for it;
- (b) appoint a manager to take full-time day to day charge of the establishment or agency in any case where the duty under regulation 11(1) is not being met; and

- (c) before the end of the period of 28 days beginning on the date of the person's appointment, notify the appropriate office of the registration authority of the person's intentions regarding the future operation of the establishment or agency to which the appointment relates.
- (2) This paragraph applies to any person appointed as—
 - (a) the receiver or manager of the property of an organisation which is a registered provider of an establishment or agency;
 - (b) a liquidator or provisional liquidator of a company which is the registered provider of an establishment or agency;
 - (c) the trustee in bankruptcy of a registered provider of an establishment or agency.

Death of registered person

35.—(1) If more than one person is registered in respect of an establishment or agency, and a registered person dies, the surviving registered person must without delay notify the appropriate office of the registration authority of the death in writing.

(2) If only one person is registered in respect of an establishment or agency, and the person dies, the person's personal representatives must notify the appropriate office of the registration authority in writing—

- (a) without delay of the death; and
- (b) within 28 days of their intentions regarding the future running of the establishment or agency.

(3) The personal representatives of the deceased registered provider may carry on the establishment or agency without being registered in respect of it—

- (a) for a period not exceeding 28 days; and
- (b) for any further period as may be determined by the registration authority in accordance with paragraph (4).

(4) The registration authority may extend the period specified in paragraph (3)(a) by such further period, not exceeding 6 months, as the registration authority may determine, and must notify any such determination to the personal representatives in writing.

(5) The personal representatives must appoint a manager to take full-time day to day charge of the establishment or agency during any period in which, in accordance with paragraph (3), they carry on the establishment or agency without being registered in respect of it.

(6) The provisions of regulation 12 apply to a manager appointed in accordance with paragraph (5).

PART IV

Additional Requirements applying to Independent Hospitals

Chapter 1

Pathology Services, Resuscitation and Treatment of Children in Independent Hospitals

Application of regulations 37 to 39

36.—(1) Regulations 37 to 39 apply to independent hospitals of the following kinds—

- (a) those defined in section 2(3)(a)(i) of the Act except establishments excepted by regulation 3(3); and
 - (b) those in which medical treatment, including cosmetic surgery, is provided under anaesthesia or sedation.
- (2) Regulation 37 also applies to any establishment which provides pathology services.

Pathology services

- 37.** The registered person must ensure that—
- (a) an adequate range of pathology services is available to meet the needs of the hospital;
 - (b) those services are provided to an appropriate standard;
 - (c) appropriate arrangements are made for the collection, and (where pathology services are provided outside the hospital) transportation of pathology specimens; and
 - (d) the patient from whom a specimen was taken, and such specimen, is identifiable at all times.

Resuscitation

38.—(1) The registered person must prepare and implement a written statement of the policies to be applied and the procedures to be followed in the hospital in relation to resuscitation of patients and must review such statement annually.

(2) The registered person must ensure that the policies and procedures implemented in accordance with paragraph (1)—

- (a) take proper account of the right of all patients who have capacity to do so to give or withhold consent to treatment;
- (b) take proper account of valid and applicable advance decisions made by patients under the 2005 Act;
- (c) are available on request to every patient and any person acting on behalf of a patient; and
- (d) are communicated to and understood by all employees and all medical practitioners with practising privileges who may be involved in decisions about resuscitation of a patient.

Treatment of children

- 39.** The registered person must ensure that, where a child is treated in the hospital—
- (a) the child is treated in accommodation which is separate from accommodation in which adult patients are treated;
 - (b) particular medical, physical, psychological, social, educational and supervision needs arising from the child's age are met;
 - (c) the child's treatment is provided by persons who have appropriate qualifications, skills and experience in the treatment of children;
 - (d) the child's parents are kept fully informed of the child's condition and so far as is practicable consulted about all aspects of the child's treatment, except where the child is competent to consent to treatment and does not wish his or her parents to be so informed and consulted.

Chapter 2

Independent Hospitals in which Certain Listed Services are Provided

Surgical procedures

40.—(1) Where medical treatment (including cosmetic surgery) is provided under anaesthesia or sedation in an independent hospital, the registered person must ensure that—

- (a) each operating theatre is designed, equipped and maintained to an appropriate standard for the purposes for which it is to be used;
- (b) all surgery is carried out by, or under the direction of, a suitably qualified, skilled and experienced medical practitioner;
- (c) an appropriate number of suitably qualified, skilled and experienced employees are in attendance during each surgical procedure; and
- (d) the patient receives appropriate treatment—
 - (i) before administration of an anaesthetic or sedation;
 - (ii) whilst undergoing a surgical procedure;
 - (iii) during recovery from general anaesthesia; and
 - (iv) post-operatively.

(2) The registered person must ensure that before a patient who has capacity to do so consents to any surgery offered by the independent hospital, the patient has received clear and comprehensive information about the procedure and any risks associated with it.

(3) In the case of a patient who lacks the capacity to consent to surgery, the information mentioned in paragraph (2) must, wherever possible, be provided to the patient's representatives.

(4) In the case of a patient who lacks capacity to consent to surgery, the registered person must take proper account of any valid and applicable advance decisions made by the patient under the 2005 Act.

Dental treatment under general anaesthesia

41. Where the treatment provided in an independent hospital includes dental treatment under general anaesthesia, the registered person must ensure that—

- (a) the dentist and any employees assisting him or her are suitably qualified, skilled and experienced to deal with any emergency which occurs during or as a result of the general anaesthesia or treatment; and
- (b) adequate facilities, drugs and equipment are available to deal with any such emergency.

Obstetric services staffing

42.—(1) This regulation and regulation 43 apply to an independent hospital in which obstetric services and, in connection with childbirth, medical services, are provided.

(2) The registered person must appoint a Head of Midwifery Services who is responsible for managing the provision of midwifery services in the independent hospital and, except in cases where obstetric services are provided in the hospital primarily by midwives, a Head of Obstetric Services whose name is included in the specialist medical register in respect of a specialty in obstetrics and who is responsible for managing the provision of obstetric services.

(3) The registered person must ensure that the health care professional who is primarily responsible for caring for pregnant women and assisting at childbirth is a midwife, an appropriately

qualified general practitioner, or a medical practitioner whose name is included in the specialist medical register in respect of a specialty in obstetrics.

(4) Where obstetric services are provided in an independent hospital primarily by midwives, the registered person must ensure that the services of a medical practitioner who is competent to deal with obstetric emergencies are available at all times.

(5) The registered person must ensure that a health care professional who is competent to undertake resuscitation of a new born baby is available in the hospital at all times and that that person's skills are regularly reviewed and, if necessary, updated.

Obstetric services further requirements

43.—(1) The registered person must ensure that—

- (a) any death of a patient in an independent hospital during, or as a result of, pregnancy or childbirth; and
- (b) any stillbirth or neonatal death in an independent hospital,

are reported to any person undertaking an enquiry into such deaths on behalf of Welsh Ministers.

(2) The registered person must ensure that facilities are available within the hospital to provide adequate treatment to patients who have undergone a delivery requiring surgical intervention or the use of forceps and that such patients are cared for by an appropriately experienced midwife.

(3) The registered person must ensure that appropriate arrangements are in place for the immediate transfer, where necessary, of a patient and her new born child to critical care facilities within the hospital or elsewhere in the near vicinity.

(4) The registered person must ensure that appropriate arrangements are in place for the treatment and, if necessary transfer to a specialist care facility, of a very sick patient or new born child.

(5) The registered person must ensure that a maternity record is maintained for each patient receiving obstetric services and each child born in the hospital, which—

- (i) includes the details specified in regulation 23(1)(a) and in Parts I and II of Schedule 4; and
- (ii) is retained for a period of not less than 25 years beginning on the date of the last entry; and the requirements of regulation 23(2) will apply to that record.

(6) In this regulation—

“stillbirth” (“*marw-enedigaeth*”) has the meaning given to it in the Births and Deaths Registration Act 1953(17);

“neonatal death” (“*marwolaeth plentyn newydd-anedig*”) means the death of a child before the end of the period of 28 days beginning with the date of the child's birth.

Termination of pregnancies

44.—(1) This regulation applies to an independent hospital in which termination of pregnancies takes place.

(2) The registered person must ensure that no patient is admitted to the hospital for termination of a pregnancy, and that no fee is demanded or accepted from a patient in respect of a termination, unless two certificates of opinion have been received in respect of the patient.

(3) The registered person must ensure that the certificates of opinion required by paragraph (2) are included with the patient's medical record, within the meaning of regulation 23.

(4) The registered person must ensure that no termination of a pregnancy is undertaken after the 20th week of gestation, unless—

- (a) the patient is treated by persons who are suitably qualified, skilled and experienced in the late termination of pregnancy; and
 - (b) appropriate procedures are in place to deal with any medical emergency which occurs during or as a result of the termination.
- (5) The registered person must ensure that no termination of a pregnancy is undertaken after the 24th week of gestation.
- (6) The registered person must ensure that a register of patients undergoing termination of a pregnancy in the hospital is maintained, which is—
- (i) separate from the register of patients which is to be maintained under paragraph 1 of Schedule 3;
 - (ii) completed in respect of each patient at the time the termination is undertaken; and
 - (iii) retained for a period of not less than three years beginning on the date of the last entry.
- (7) The registered person must prepare and implement appropriate procedures in the hospital to ensure that foetal tissue is treated with respect.
- (8) In this regulation, “certificate of opinion” (“*tystysgrif barn*”) means a certificate required by regulations made under section 2(1) of the Abortion Act 1967(18).

Use of certain techniques or technology

- 45.—**(1) The registered person must ensure that no Class 3B or Class 4 laser product (within the meaning of regulation 3(1)), or intense light source (within the meaning of that regulation) is used in or for the purposes of an independent hospital unless that hospital has in place a professional protocol drawn up by a trained and experienced medical practitioner or dentist from the relevant discipline in accordance with which treatment is to be provided, and that the treatment is provided in accordance with it.
- (2) The registered person must maintain at the establishment a register of each occasion when a technique or technology referred to in paragraph (1) has been used which includes—
- (a) the name of the patient in connection with whose treatment the technique or technology was used;
 - (b) the nature of the technique or technology in question and the date on which it was used;
 - (c) the name of the person using it; and
 - (d) where the person using the technique or technology is not a medical practitioner, dentist or other competent person, the name and relevant qualifications of the medical practitioner or dentist who compiled the professional protocol referred to in paragraph (1).
- (3) The registered person must ensure that such a laser product or intense light source is used in or for the purposes of the independent hospital only by a person who has undertaken appropriate training and has demonstrated an understanding of—
- (a) the correct use of the equipment in question;
 - (b) the risks associated with using a laser product or intense light source;
 - (c) its biological and environmental effects;
 - (d) precautions to be taken before and during use of a laser product or intense light source; and
 - (e) action to be taken in the event of an accident, emergency, or other adverse incident.

Chapter 3

Mental Health Hospitals

Application of regulations 47 to 50

- 46.** Regulations 47 to 50 apply to independent hospitals of the following kinds—
- (a) those the main purpose of which is to provide medical or psychiatric treatment for mental disorder; and
 - (b) those in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983.

Safety of patients and others

47.—(1) The statement of policies and procedures which is to be prepared and implemented by the registered person in accordance with regulation 9(1)(e) must include policies and procedures in relation to—

- (a) assessment of a patient's propensity to violence and self harm;
- (b) the provision of information to employees as to the outcome of such an assessment;
- (c) assessment of the effect of the layout of the hospital premises, and its policies and procedures, on the risk of a patient harming himself or another person; and
- (d) the provision of training to enable employees to minimise the risk of a patient harming himself or another person.

(2) The registered person must in particular prepare and implement a suicide protocol in the hospital which requires—

- (a) a comprehensive examination of the mental condition of each patient;
- (b) an evaluation of the patient's history of mental disorder, including identification of suicidal tendencies;
- (c) an assessment of the patient's propensity to suicide; and
- (d) if necessary, appropriate action to reduce the risk of the patient committing suicide.

Visitors

48. The registered person must prepare and implement written policies and procedures in the hospital in relation to patients receiving visitors.

Mental health records

49. The registered person must ensure that any records which are required to be made under the Mental Health (Hospital, Guardianship, Community Treatment and Consent to Treatment) (Wales) Regulations 2008(19), and which relate to the detention or treatment of a patient in an independent hospital, are kept for a period of not less than five years beginning on the date on which the person to whom they relate ceases to be a patient in the hospital.

PART V

Additional Requirements Applying to Independent Clinics

Independent clinics

50. Where an independent clinic provides antenatal care to patients, the registered person must ensure that the health care professional who is primarily responsible for providing that care is a midwife, an appropriately qualified general practitioner, or a medical practitioner with a specialist qualification in obstetrics.

PART VI

Miscellaneous

Compliance with regulations

51. Where there is more than one registered person in respect of an establishment or agency, anything which is required under these regulations to be done by the registered person will, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Offences

52.—(1) A contravention, or failure to comply with any of the provisions of regulation 6 to 17, 18(1), 19 to 35, 37 to 45 and 47 to 50 will be an offence.

(2) The registration authority may bring proceedings against a person who was once, but no longer is, a registered person, in respect of a failure to comply with regulation 23 after the person ceased to be a registered person.

Transitional provisions

53.—(1) Until such time as an intervening event takes place, regulation 27 does not apply to a person registered in respect of an independent hospital or to an applicant for registration as a manager where the registration of the registered provider was granted prior to 5 April 2011.

(2) For the purposes of this regulation, an “intervening event” (*“digwyddiad cyfamserol”*) is—

- (a) an application received by the registration authority under section 12 of the Act from a new provider of the independent hospital; or
- (b) an application received by the registration authority under section 15(1)(a) of the Act from a registered person and the effect of the application being granted would be as specified in paragraph (3).

(3) There is an increase in the number of approved places that the registered person can provide to patients who have a diagnosed learning disability.

(4) In the case of an intervening event under paragraph (2)(b), regulation 52 will not apply to regulation 27 until such time as the application is finally disposed of or withdrawn.

(5) For the purpose of paragraph (4) “finally disposed of” (*“cael ei benderfynu'n derfynol”*) means the grant of the application under section 15(4) or, in the case of a refusal of the application, the date 28 days following the refusal of the application and, if an appeal is made, the date when the appeal is finally determined or abandoned.

(6) Paragraph (7) applies to persons registered in respect of an establishment prior to 5 April 2011 where—

- (a) regulation 3 applies such that the independent hospital is no longer an independent hospital; and
 - (b) regulation 4 applies in relation to that establishment.
- (7) Persons to whom paragraph (6) applies—
- (a) may continue to carry on or manage the establishment without being registered under the Act—
 - (i) during a period of 3 months beginning the 5 April 2011; and
 - (ii) if within that period application is made for registration, until the application is finally disposed of or withdrawn;
 - (b) are excepted from payment of a registration fee under regulation 3 of the Independent Health Care (Fees) (Wales) Regulations 2011⁽²⁰⁾.
- (8) For the purposes of paragraph (7)(a)(ii) “finally disposed of” (“cael ei benderfynu'n derfynol”) means the date 28 days following the grant or refusal of registration and, if an appeal is made, the date when the appeal is finally determined or abandoned.

Revocation and savings

54.—(1) Subject to paragraph (2) the Private and Voluntary Health Care (Wales) Regulations 2002⁽²¹⁾ (“the 2002 Regulations”) are hereby revoked.

(2) Regulation 3(4) of the 2002 Regulations continues to have effect.

10 March 2011

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

⁽²⁰⁾ S.I. 2011/106 (W.25).

⁽²¹⁾ S.I. 2002/325 (W.38).