#### WELSH STATUTORY INSTRUMENTS

# 2011 No. 734

# The Independent Health Care (Wales) Regulations 2011

#### **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(1);

"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(2).

#### 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;

<sup>(1) 1953</sup> c. 20.

<sup>(2) 1967</sup> c. 87.

- (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(3), 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.