
STATUTORY INSTRUMENTS

2001 No. 3968

The Private and Voluntary Health
Care (England) Regulations 2001

PART IV

ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT HOSPITALS

CHAPTER 1

PATHOLOGY SERVICES, RESUSCITATION AND
TREATMENT OF CHILDREN IN INDEPENDENT HOSPITALS

Application of regulations 34 to 36

- 33.**—(1) Regulations 34 to 36 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(2); and
 - (b) those in which medical treatment, including cosmetic surgery, is provided under anaesthesia or sedation.
- (2) Regulation 34 also applies to any establishment or agency which provides pathology services.

Pathology services

- 34.** The registered person shall ensure that—
- (a) an adequate range of pathology services is available to meet the needs of the independent 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

35.—(1) The registered person shall 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 shall review such statement annually.

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

- (a) take proper account of the right of all patients who are competent to do so to give or withhold consent to treatment;
- (b) are available on request to every patient and any person acting on behalf of a patient; and

- (c) 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

- 36.** The registered person shall ensure that, where a child is treated in an independent hospital—
- (a) he 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 his age are met;
 - (c) his treatment is provided by persons who have appropriate qualifications, skills and experience in the treatment of children;
 - (d) his parents are kept fully informed of his condition and so far as is practicable consulted about all aspects of his treatment, except where the child is himself competent to consent to treatment and does not wish his parents to be so informed and consulted.

CHAPTER 2

INDEPENDENT HOSPITALS IN WHICH CERTAIN LISTED SERVICES ARE PROVIDED

Surgical procedures

37.—(1) Where medical treatment (including cosmetic surgery) is provided under anaesthesia or sedation in an independent hospital, the registered person shall 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 shall ensure that before a patient consents to any surgery offered by the independent hospital, he has received clear and comprehensive information about the procedure and any risks associated with it.

(3) In the case of a patient who is not competent to consent to surgery, the information mentioned in paragraph (2) shall, wherever possible, be provided to his representatives.

Dental treatment under general anaesthesia

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

- (a) the dentist and any employees assisting him 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

39.—(1) This regulation and regulation 40 apply to an independent hospital in which obstetric services and, in connection with childbirth, medical services are provided.

(2) The registered person shall appoint a Head of Midwifery Services who is responsible for managing the provision of midwifery services in an 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 shall 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 shall 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 shall 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 his skills are regularly reviewed and, if necessary, updated.

Obstetric services—further requirements

40.—(1) The registered person shall ensure that—

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

are reported to any person undertaking an enquiry into such deaths on behalf of the Secretary of State⁽¹⁾.

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

- (a) includes the details specified in regulation 21(1)(a) and in Parts I and II of Schedule 4; and
- (b) is retained for a period of not less than 25 years beginning on the date of the last entry,

and the requirements of regulation 21(2) shall apply to that record.

(6) In this regulation—

“still-birth” has the meaning given to it in the Births and Deaths Registration Act 1953⁽²⁾;

(1) The Confidential Enquiry into Maternal Deaths and the Confidential Enquiry into Stillbirths and Deaths in Infancy are currently undertaken on behalf of the Secretary of State for Health by the National Institute for Clinical Excellence.

(2) 1953 c. 20. See section 41, as amended by the Still-Birth (Definition) Act 1992 (c. 29), section 1(1).

“neonatal death” 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

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

(2) The registered person shall 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 shall ensure that a certificate of opinion in respect of a patient undergoing termination of a pregnancy is completed and included with the patient’s record, within the meaning of regulation 21.

(4) The registered person shall 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 shall ensure that no termination of a pregnancy is undertaken after the 24th week of gestation.

(6) The registered person shall ensure that a register of patients undergoing termination of a pregnancy in the hospital is maintained, which is—

- (a) separate from the register of patients which is to be maintained under paragraph 1 of Schedule 3;
- (b) completed in respect of each patient at the time the termination is undertaken; and
- (c) retained for a period of not less than three years beginning on the date of the last entry.

(7) The registered person shall ensure that a record is maintained of the total numbers of terminations undertaken in the hospital; and the requirements of regulation 21(3) shall apply to that record.

(8) The registered person shall ensure that notice in writing is sent to the Chief Medical Officer of the Department of Health of each termination of pregnancy which takes place in the hospital⁽³⁾.

(9) If the registered person—

- (a) receives information concerning the death of a patient who has undergone termination of a pregnancy in the 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,

he shall give notice in writing to the Commission of that information, within the period of 14 days beginning on the day on which the information is received.

(10) The registered person shall prepare and implement appropriate procedures in the hospital to ensure that fetal tissue is treated with respect.

(11) In this regulation, “certificate of opinion” means a certificate required by regulations made under section 2(1) of the Abortion Act 1967⁽⁴⁾.

⁽³⁾ See S.I. 1991/499, which requires such notice to be given by the medical practitioner carrying out the termination.

⁽⁴⁾ 1967 c. 87. See S.I. 1991/499.

Use of certain techniques or technology

42.—(1) The registered person shall ensure that no Class 3B or Class 4 laser or intense light source (within the meaning of regulation 3(1)), 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 is so provided.

(2) The registered person shall ensure that such a laser or intense light source is used in or for the purposes of the 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 or intense light source;
- (c) its biological and environmental effects;
- (d) precautions to be taken before and during use of a laser 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 44 to 47

43. Regulations 44 to 47 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(5).

Safety of patients and others

44.—(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) shall 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 shall 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.

Management of disturbed behaviour

45. The registered person shall 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.

Visitors

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

Mental health records

47. The registered person shall ensure that any records which are required to be made under the Mental Health (Hospital, Guardianship and Consent to Treatment) Regulations 1983⁽⁶⁾, 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.

(6) S.I. 1983/893, as amended.