
STATUTORY INSTRUMENTS

2001 No. 3968

PUBLIC HEALTH, ENGLAND

**The Private and Voluntary Health
Care (England) Regulations 2001**

Made - - - - *11th December 2001*
Laid before Parliament *12th December 2001*
Coming into force - - *1st April 2002*

The Secretary of State, in exercise of powers conferred on him by sections 2(4), (7)(f) and (8), 22(1), (2)(a) to (d), (f) to (j), (5)(a) and (7)(a) to (h), (j) and (k), 25(1), 34(1), 35(1) and 118(5) to (7) of the Care Standards Act 2000⁽¹⁾ and of all other powers enabling him in that behalf, having consulted such persons as he considers appropriate⁽²⁾, hereby makes the following Regulations:—

PART I
GENERAL

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Private and Voluntary Health Care (England) Regulations 2001 and shall come into force on 1st April 2002.

(2) These Regulations extend to England only.

Interpretation

2.—(1) In these Regulations—

“the Act” means the Care Standards Act 2000;

“agency” means an independent medical agency;

“dentist” means a person registered in the dentists register under the Dentists Act 1984⁽³⁾;

(1) 2000 c. 14. The powers are exercisable by the appropriate Minister, who is defined in section 121(1), in relation to England, Scotland and Northern Ireland, as the Secretary of State, and in relation to Wales, as the National Assembly for Wales. “Prescribed” and “regulations” are defined in section 121(1) of the Act.

(2) See section 22(9) of the Care Standards Act 2000 for the requirement to consult.

(3) 1984 c. 24.

“establishment” means an independent hospital, including an independent hospital in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983(4), or an independent clinic;

“general practitioner” means a medical practitioner who—

- (a) provides general medical services within the meaning of Part II of the NHS Act;
- (b) performs personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997(5); or
- (c) provides services which correspond to services provided under Part II of the NHS Act, otherwise than in pursuance of that Act;

“health care professional” means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(6) applies, or who is a clinical psychologist or child psychotherapist, and “health care profession” shall be construed accordingly;

“medical device” has the same meaning as in the Medical Devices Regulations 1994(7);

“medical practitioner” means a registered medical practitioner(8);

“midwife” means a registered midwife(9) who has notified her intention to practise to the local supervisory authority in accordance with any rules made under section 14(1)(b) of the Nurses, Midwives and Health Visitors Act 1997(10);

“the NHS Act” means the National Health Service Act 1977(11);

“organisation” means a body corporate or any unincorporated association other than a partnership;

“patient”, in relation to any 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” means the guide compiled in accordance with regulation 7;

“practising privileges” 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”, 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”, 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”, 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” shall be construed in accordance with regulation 10(2)(b)(i);

“statement of purpose” means the written statement compiled in accordance with regulation 6;

“treatment” includes palliative care and nursing and listed services within the meaning of section 2 of the Act(12).

(2) In these Regulations, a reference—

(4) 1983 c. 20.

(5) 1997 c. 46.

(6) 1999 c. 8.

(7) S.I.1994/3017.

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

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

(10) 1997 c. 24.

(11) 1977 c. 49.

(12) See section 2(7).

- (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.

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

Prescribed techniques or technology and exceptions to the definition of independent hospital

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

- (a) a Class 3B or Class 4 laser product, as defined in Part I of British Standard EN 60825–1 (Radiation safety of laser products and systems)**(13)**;
- (b) an intense light, being broadband non-coherent light which is filtered to produce a specified range of wavelengths; such filtered radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues;
- (c) haemodialysis or peritoneal dialysis;
- (d) endoscopy;
- (e) hyperbaric oxygen therapy, being the administration of pure oxygen through a mask to a patient who is in a sealed chamber which is gradually pressurised with compressed air, except where the primary use of that chamber is—
 - (i) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997**(14)** or regulation 8 or 12 of the Work in Compressed Air Regulations 1996**(15)**; or
 - (ii) otherwise for the treatment of workers in connection with the work which they perform; and
- (f) in vitro fertilisation techniques, being treatment services for which a licence may be granted under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990**(16)**.

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

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

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

- (a) an establishment which is a hospital by virtue of section 2(3)(a)(i) of the Act solely because its main purpose is to provide medical or psychiatric treatment for illness or mental disorder but which provides no overnight beds for patients;

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

(14) S.I. 1997/2776.

(15) S.I. 1996/1656.

(16) 1990 c. 37.

- (b) an establishment which is a service hospital within the meaning of section 13(9) of the Armed Forces Act 1981⁽¹⁷⁾;
 - (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⁽¹⁸⁾;
 - (d) an establishment which is an independent clinic by virtue of regulation 4;
 - (e) an establishment (not being a health service hospital) which has as its sole or main purpose the provision by a general practitioner of general medical services within the meaning of Part II of the NHS Act or personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and such an establishment shall not become an independent hospital as a result of the provision of listed services to a patient by such a general practitioner;
 - (f) the private residence of a patient or patients in which treatment is provided to such patient or patients, but to no-one else;
 - (g) sports grounds and gymnasia where health professionals provide treatment to persons taking part in sporting activities and events; and
 - (h) a surgery or consulting room, not being part of a hospital, where a medical practitioner provides medical services solely under arrangements made on behalf of the patients by their employer or another person.
- (4) Sub-section (7) of section 2 of the Act shall be modified by adding at the end of paragraph (e) (cosmetic surgery) the following—
- “(a) other than—
 - (i) ear and body piercing;
 - (ii) tattooing;
 - (iii) the subcutaneous injection of a substance or substances into the skin for cosmetic purposes; and
 - (iv) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.”.

Meaning of independent clinic

4.—(1) For the purposes of section 2(4) of the Act, establishments of the following kinds are prescribed—

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

(2) Where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical

⁽¹⁷⁾ 1981 c. 55.

⁽¹⁸⁾ 1952 c. 52. Amended by section 170(1) of and paragraphs 11 and 12 of Schedule 15, and Schedule 16, to the Criminal Justice Act 1988 (c. 33); sections 5(2), 18(3) and 168(3) of, and Schedule 11 to, the Criminal Justice and Public Order Act 1994 (c. 33); section 119 of, and paragraph 6 of Schedule 8 to, the Crime and Disorder Act 1998 (c. 37); and section 165(1) of, and paragraph 5 of Schedule 9 to, the Powers of the Criminal Courts (Sentencing) Act 2000 (c. 6). Subsection (1)(a) of section 43 is to be repealed by sections 59 and 75 of, and Schedule 8 to, the Criminal Justice and Court Services Act 2000 (c. 43) on a date to be appointed.

practitioners shall 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 solely under arrangements made on behalf of the patients by their employer or another person shall be excepted from being an independent medical agency.

Statement of purpose

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

(2) The registered person shall supply a copy of the statement of purpose to the Commission and shall make the statement available for inspection by every patient and any person acting on behalf of a patient.

(3) Nothing in regulation 15(1) or 25(1) and (2) shall require or authorise the registered person to contravene, or not to 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 shall produce a written guide to the establishment or agency (in these Regulations referred to as “the patients' guide”) which shall consist of—

- (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 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 23;
- (e) a summary of the results of the consultation conducted in accordance with regulation 17(3);
- (f) the address and telephone number of the Commission; and
- (g) the most recent inspection report prepared by the Commission or information as to how a copy of that report may be obtained.

(2) The registered person shall supply a copy of the patients' guide to the Commission, and shall make the patients' guide available for inspection by every patient and any person acting on behalf of a patient.

Review of statement of purpose and patients' guide

8. The registered person shall—

- (a) keep under review and, where appropriate, revise the statement of purpose and the content of the patients' guide; and
- (b) notify the Commission of any such revision.

Policies and procedures

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

- (a) the arrangements for admission or acceptance of patients, their transfer to a hospital where required and, in the case of an establishment which admits in-patients, their discharge;
- (b) the arrangements for assessment, diagnosis and treatment of patients;
- (c) ensuring that the premises used by or for the purposes of an establishment are at all times fit for the purpose for which they are used;
- (d) monitoring the quality and suitability of facilities and equipment;
- (e) identifying, assessing and managing risks to employees, patients and visitors associated with the operation 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) the grant and withdrawal of practising privileges to medical practitioners in establishments where such privileges are granted; and
- (j) ensuring that, where research is carried out in an establishment, it is carried out with the consent of any patient or patients involved, is appropriate for the establishment concerned and is conducted in accordance with up-to-date and authoritative published guidance on the conduct of research projects.

(2) The registered person shall prepare and implement a written statement of the policies to be applied and the procedures to be followed for the purposes of an agency in relation to—

- (a) the arrangements for transfer to a hospital, where required; and
- (b) each of the matters specified in sub-paragraphs (b), (f), (g) and (h) of paragraph (1).

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

- (a) the competence of each patient to consent to treatment is assessed;
- (b) in the case of a competent patient, properly informed consent to treatment is obtained;
- (c) in the case of a patient who is not competent, he is, so far as practicable, consulted before any treatment proposed for him is administered; and
- (d) information about a patient's health and treatment is disclosed only to those persons who need to be aware of that information in order to treat the patient effectively or minimise any risk of the patient harming himself or another person, or for the purposes of the proper administration of the establishment or agency.

(4) The registered person shall review the operation of each policy and procedure implemented under—

- (a) this regulation;
- (b) regulation 23; and
- (c) in so far as they apply to him, regulations 35, 41(10), 45 and 46,

at intervals of not more than three years and shall, where appropriate, prepare and implement revised policies and procedures.

(5) The registered person shall make a copy of all written statements prepared in accordance with this regulation available for inspection by the Commission.

PART II

REGISTERED PERSONS

Fitness of registered provider

- 10.**—(1) A person shall not carry on an establishment or agency unless he 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 carries on the establishment or agency—
 - (i) otherwise than in partnership with others, and he satisfies the requirements set out in paragraph (3);
 - (ii) in partnership with others, and he and each of his partners satisfies the requirements set out in paragraph (3);
 - (b) is a partnership, and each of the partners satisfies the requirements set out in paragraph (3);
 - (c) is an organisation and—
 - (i) the organisation has given notice to the Commission 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) he is of integrity and good character;
 - (b) he is physically and mentally fit to carry on the establishment or agency; and
 - (c) full and satisfactory information is available in relation to him—
 - (i) except where paragraph (4) applies, in respect of each of the matters specified in paragraphs 1 to 7 of Schedule 2;
 - (ii) where paragraph (4) applies, in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.
- (4) This paragraph applies where any certificate or information on any matters referred to in paragraph 2 of Schedule 2 is not available to an individual because any provision of the Police Act 1997⁽¹⁹⁾ has not been brought into force.
- (5) A person shall not carry on an establishment or agency if—
- (a) he has been adjudged bankrupt or sequestration of his estate has been awarded and (in either case) he has not been discharged and the bankruptcy order has not been annulled or rescinded; or
 - (b) he has made a composition or arrangement with his creditors and has not been discharged in respect of it.

Appointment of manager

- 11.**—(1) The registered provider shall appoint an individual to manage an establishment or agency if—
- (a) there is no registered manager in respect of the establishment or agency; and

⁽¹⁹⁾ 1997 c. 50. Sections 113 and 115, as amended, have not yet been brought into force. See the footnotes to paragraph 2 of Schedule 2.

- (b) the registered provider—
 - (i) is an organisation or a partnership;
 - (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) Where the registered provider appoints a person to manage the establishment or agency, he shall forthwith give notice to the Commission of—

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

Fitness of registered manager

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

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

- (a) he is of integrity and good character;
- (b) having regard to the size of the establishment or agency and the number and needs of the patients—
 - (i) he has the qualifications, skills and experience necessary to manage the establishment or agency; and
 - (ii) he is physically and mentally fit to do so; and
- (c) full and satisfactory information is available in relation to him—
 - (i) except where paragraph (3) applies, in respect of each of the matters specified in paragraphs 1 to 7 of Schedule 2;
 - (ii) where paragraph (3) applies, in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.

(3) This paragraph applies where any certificate or information on any matters referred to in paragraph 2 of Schedule 2 is not available to an individual because any provision of the Police Act 1997⁽²⁰⁾ has not been brought into force.

Registered person—general requirements

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

(2) If the registered provider is—

- (a) an individual, he shall undertake;
- (b) an organisation, it shall ensure that the responsible individual undertakes;
- (c) a partnership, it shall ensure that one of the partners undertakes,

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

(3) The registered manager shall undertake from time to time such training as is appropriate to ensure that he has the skills necessary for managing the establishment or agency.

⁽²⁰⁾ See footnote to regulation 10(4).

Notification of offences

14. Where the registered person or the responsible individual is convicted of any criminal offence, whether in England and Wales or elsewhere, he shall forthwith give notice in writing to the Commission of—

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

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(3), the registered person shall provide treatment and any other services to patients in accordance with the statement of purpose, and shall ensure that the treatment and any other services provided to each patient—

- (a) meet his individual needs;
- (b) reflect published research evidence and guidance issued by the appropriate professional and expert bodies, as to good practice in the treatment of the condition from which the patient is suffering; and
- (c) are (where necessary) provided by means of appropriate equipment.

(2) The registered person shall ensure that all equipment used in or for the purposes of the establishment, or for the purposes of the agency is—

- (a) suitable for the purposes for which it is to be used; and
- (b) properly maintained and in good working order.

(3) Where reusable medical devices are used in an establishment or agency, the registered person shall 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) shall be such as to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.

(5) The registered person shall make suitable arrangements for the ordering, recording, handling, safe keeping, safe administration and disposal of medicines used in or for the purposes of the establishment, or for the purposes of the agency.

(6) The registered person shall make suitable arrangements to minimise the risk of infection and toxic conditions and the spread of infection between patients and staff (including medical practitioners with practising privileges).

(7) If an establishment provides food for patients, the registered provider shall ensure that it is—

- (a) provided in adequate quantities and at appropriate intervals;
- (b) properly prepared, wholesome and nutritious; and
- (c) suitable for the needs of patients,

and that the menu is varied at suitable intervals.

Care and welfare of patients

16.—(1) The registered person shall, so far as practicable, enable each patient to make decisions about matters affecting the way in which he is cared for and his general welfare.

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

(3) The registered person shall, so far as practicable, 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.

(4) The registered person shall 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 and spiritual needs, racial origin, and cultural and linguistic background and any disability of patients.

(5) The registered provider and the registered manager (if any) shall 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.

Review of quality of treatment and other services

17.—(1) The registered person shall introduce and maintain a system for reviewing at appropriate intervals the quality of treatment and other services provided in or for the purposes of an establishment or for the purposes of an agency.

(2) The registered person shall supply to the Commission a report in respect of any review conducted by him for the purposes of paragraph (1) and make a copy of the report available to patients.

(3) The system referred to in paragraph (1) shall provide for consultation with patients and their representatives.

Staffing

18.—(1) The registered person shall, having regard to the nature of the establishment or agency and the number and needs of patients, ensure that there is at all times an appropriate number of suitably qualified, skilled and experienced persons employed in or for the purposes of the establishment or, as the case may be, for the purposes of the agency.

(2) The registered person shall 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 he performs; and
- (c) is provided with a job description outlining his responsibilities.

(3) The registered person shall 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 shall 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 shall take reasonable steps to ensure that any person working in an establishment or agency who is not employed by him and to whom paragraph (2) does not apply, is appropriately supervised while carrying out his duties.

Fitness of workers

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

- (a) no person is employed to work in or for the purposes of the establishment or for the purposes of the agency; and
- (b) no medical practitioner is granted consulting or practising privileges,

unless that person is fit to work in or for the purposes of the establishment, or for the purposes of the agency.

(2) A person is not fit to work in or for the purposes of an establishment, or for the purposes of an agency unless—

- (a) he is of integrity and good character;
- (b) he has the qualifications, skills and experience which are necessary for the work which he is to perform;
- (c) he is physically and mentally fit for that work; and
- (d) full and satisfactory information is available in relation to him—
 - (i) except where paragraph (3) applies, in respect to each of the matters specified in paragraphs 1 to 7 of Schedule 2;
 - (ii) where paragraph (3) applies, in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.

(3) This paragraph applies where any certificate or information on any matters referred to in paragraph 2 of Schedule 2 is not available to an individual because any provision of the Police Act 1997⁽²¹⁾ has not been brought into force.

Guidance for health care professionals

20. The registered person shall 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

21.—(1) The registered person shall ensure that except in cases to which regulation 40(5) applies—

- (a) a comprehensive medical record is maintained in relation to each patient, which includes—
 - (i) a contemporaneous note of all treatment provided to him;
 - (ii) his medical history and all other notes prepared by a health care professional about his case; and

(21) See footnote to regulation 10(4).

- (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 shall ensure that—
 - (a) the medical record for a person who is currently a patient is kept in a secure place in the establishment or the agency premises; and
 - (b) the medical record for a person who is not currently a patient is stored securely (whether in the establishment or the agency premises or elsewhere) and that it can be located if required.
- (3) The registered person shall ensure that the records 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 the agency premises by any person authorised by the Commission to enter and inspect the establishment or agency premises; and
 - (c) retained for a period of not less than three years beginning on the date of the last entry.

Staff views as to conduct of establishment or agency

22.—(1) This regulation applies to any matter relating to the conduct of the establishment or agency so far as it may affect the health and welfare of patients.

(2) The registered person shall make arrangements to enable any person employed in or for the purposes of the establishment, or for the purposes of the agency, and any medical practitioner with practising privileges to inform the registered person and the Commission of their views about any matter to which this regulation applies.

Complaints

23.—(1) The registered person shall 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 shall ensure that any complaint made under the complaints procedure is fully investigated.

(3) The registered person shall supply a written copy of the complaints procedure to every patient and, upon request, to—

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

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

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

(5) The registered person shall maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence and the requirements of regulation 21(3)(b) and (c) shall apply to that record.

(6) The registered person shall supply to the Commission annually a statement containing a summary of the complaints made during the preceding twelve months and the action taken in response.

Research

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

- (a) before any research involving patients, information about patients, or bodily material and organs is undertaken in or for the purposes of an establishment, or for the purposes of an agency, 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” means a research ethics committee established in accordance with guidance issued from time to time by the Department of Health.

CHAPTER 2

PREMISES

Fitness of premises

25.—(1) Subject to regulation 6(3), the premises used as an establishment or agency must be 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 shall ensure that—

- (a) the premises are of sound construction and kept in a good state of repair externally and internally;
- (b) the size and layout of rooms are suitable for the purposes for which they are to be used and are suitably equipped and furnished;
- (c) all parts of the establishment or agency are kept clean and meet appropriate standards of hygiene;
- (d) all parts of the establishment or agency to which patients have access are so far as reasonably practicable free from hazards to their safety; and
- (e) 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 or agency, 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 shall 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) The registered person shall, after consultation with the fire authority—

- (a) take adequate precautions against the risk of fire, including the provision and maintenance of suitable fire equipment;
- (b) provide adequate means of escape in the event of a fire;
- (c) make arrangements for persons employed in the establishment or for the purposes of the agency 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 or for the purposes of the agency 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; and
- (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.

(5) In this regulation “fire authority”, in relation to an establishment or agency, means the authority discharging in the area in which the establishment or agency is situated, the function of fire authority under the Fire Services Act 1947(22).

CHAPTER 3

MANAGEMENT

Visits by registered provider

26.—(1) Where the registered provider is an individual, but is not in day to day charge of the establishment or agency, he shall visit the establishment or agency premises in accordance with this regulation.

(2) Where the registered provider is an organisation or a partnership, the establishment or agency shall be visited in accordance with this regulation by—

- (a) the responsible individual or one of the partners, as the case may be;
- (b) another of the directors or other persons responsible for the management of the organisation or partnership; or
- (c) an employee of the organisation or partnership who is not directly concerned with the conduct of the establishment or agency.

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

(4) The person carrying out the visit shall—

- (a) interview, with their consent and in private (if necessary, by telephone), such of the patients and their representatives and such employees as appears to him 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, or for the purposes of the agency;
- (b) inspect records of any complaints and, in the case of an establishment, its premises; and
- (c) prepare a written report on the conduct of the establishment or agency.

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

- (a) the Commission;
- (b) the registered manager; and
- (c) in the case of a visit under paragraph (2)—
 - (i) where the registered provider is an organisation, to each of the directors or other persons responsible for the management of the organisation; and
 - (ii) where the registered provider is a partnership, to each of the partners.

Financial position

27.—(1) The registered provider shall 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 shall, if the Commission so requests, provide the Commission 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 shall also provide the Commission 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 him 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 COMMISSION

Notification of events

28.—(1) The registered person shall give notice to the Commission of—

- (a) the death of a patient—
 - (i) in an establishment;
 - (ii) during treatment provided by an establishment or agency; or
 - (iii) as a consequence of treatment provided by an establishment or agency within the period of seven days ending on the date of the death, and the circumstances of his 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 the agency, or any medical practitioner with practising privileges.

(2) Notice under paragraph (1) shall be given within the period of 24 hours beginning with the event in question and, if given orally, shall be confirmed in writing as soon as practicable.

Notice of absence

29.—(1) Where—

- (a) the registered provider, if he is the person in day to day charge of the establishment or agency; or
- (b) the registered manager,

proposes to be absent from the establishment or agency for a continuous period of 28 days or more, the registered person shall give notice in writing to the Commission of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) shall be given no later than one month before the proposed absence commences or within such shorter period as may be agreed with the Commission and the notice shall specify with respect to the proposed 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
- (e) in the case of the absence of the registered manager, 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 shall give notice of the absence within one week of its occurrence specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(4) Where—

- (a) the registered provider, if he is the person in day to day charge of the establishment or agency; or
- (b) the registered manager,

has been absent from the establishment or agency for a continuous period of 28 days or more, and the Commission has not been given notice of the absence, the registered person shall, without delay, give notice in writing to the Commission of the absence, specifying the matters set out in paragraph (2) (a) to (e).

(5) The registered person shall notify the Commission of the return to duty of the registered provider or (as the case may be) the registered manager not later than 7 days after the date of his return.

Notice of changes

30. The registered person shall give notice in writing to the Commission 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 changes his name;
- (d) where the registered provider is a partnership, there is any change in the membership of the partnership;
- (e) 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;
- (iii) there is any change in the identity of the responsible individual;
- (f) where the registered provider is an individual, a trustee in bankruptcy is appointed;
- (g) where the registered provider is a company or partnership, a receiver, manager, liquidator or provisional liquidator is appointed; or
- (h) the premises of the establishment or agency are significantly altered or extended, or additional premises are acquired.

Appointment of liquidators etc.

- 31.**—(1) Any person to whom paragraph (2) applies must—
- (a) forthwith notify the Commission of his 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 there is no registered manager; and
 - (c) before the end of the period of 28 days beginning on the date of his appointment, notify the Commission of his intentions regarding the future operation of the establishment or agency.
- (2) This paragraph applies to any person appointed as—
- (a) the receiver or manager of the property of a company or partnership which is a registered provider of an establishment or agency;
 - (b) 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

32.—(1) If more than one person is registered in respect of an establishment or agency, and a registered person dies, the surviving registered person shall without delay notify the Commission of the death in writing.

(2) If only one person is registered in respect of an establishment or agency, and he dies, his personal representatives must notify the Commission 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 in accordance with paragraph (4).

(4) The Commission may extend the period specified in paragraph (3)(a) by such further period, not exceeding one year, as the Commission shall determine, and shall notify any such determination to the personal representatives in writing.

(5) The personal representatives shall appoint a person 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.

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⁽²³⁾.

(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⁽²⁴⁾;

“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.

⁽²³⁾ 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.

⁽²⁴⁾ 1953 c. 20. See section 41, as amended by the Still-Birth (Definition) Act 1992 (c. 29), section 1(1).

(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⁽²⁵⁾.

(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⁽²⁶⁾.

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—

⁽²⁵⁾ See S.I. 1991/499, which requires such notice to be given by the medical practitioner carrying out the termination.

⁽²⁶⁾ 1967 c. 87. See S.I. 1991/499.

- (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(27).

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(28), 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

48. Where an independent clinic provides antenatal care to patients, the registered person shall 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

ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT MEDICAL AGENCIES

Independent medical agencies

49. The registered person shall ensure that the register of patients to be maintained in relation to an independent medical agency under paragraph 1 of Schedule 3 includes the name of the medical practitioner by whom each patient is treated.

PART VII

MISCELLANEOUS

Compliance with regulations

50. 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 shall, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Offences

51.—(1) A contravention, or failure to comply with, any of the provisions of regulations 6, 7, 9, 14, 15, 16(1) to (4), 17 to 32, 34 to 42 and 44 to 49 shall be an offence.

(2) The Commission shall not bring proceedings against a person in respect of any contravention or failure to comply with those regulations unless—

- (a) subject to paragraph (4), he is a registered person;
- (b) notice has been given to him in accordance with paragraph (3);
- (c) the period specified in the notice, beginning with the date of the notice has expired; and
- (d) the person contravenes or fails to comply with any of the provisions of the regulations mentioned in the notice.

(3) Where the Commission considers that the registered person has contravened or failed to comply with any of the provisions of the regulations mentioned in paragraph (1), it may serve a notice on the registered person specifying—

- (a) in what respect in its opinion the registered person has contravened or is contravening any of the regulations, or has failed or is failing to comply with the requirements of any of the regulations;
- (b) what action, in the opinion of the Commission, the registered person should take so as to comply with any of those regulations; and
- (c) the period, not exceeding three months beginning on the date on which the notice is given, within which the registered person should take action.

(4) The Commission 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 21 and for this purpose, references in paragraphs (2) and (3) to a registered person shall be taken to include such a person.

Signed by authority of the Secretary of State for Health

11th December 2001

Jacqui Smith
Minister of State,
Department of Health

SCHEDULE 1

Regulation 6

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

1. The aims and objectives of the establishment or agency.
2. The name and address of the registered provider and of any registered manager.
3. The relevant qualifications and experience of the registered provider and any registered manager.
4. The number, relevant qualifications and experience of the staff working in the establishment, or for the purposes of the agency.
5. The organisational structure of the establishment or agency.
6. The kinds of treatment and any other services provided for the purposes of the establishment or agency, the range of needs which those services are intended to meet and the facilities which are available for the benefit of patients.
7. The arrangements made for consultation with patients about the operation of the establishment or agency.
8. The arrangements made for contact between any in-patients and their relatives, friends and representatives.
9. The arrangements for dealing with complaints.
10. The arrangements for respecting the privacy and dignity of patients.

SCHEDULE 2

Regulations 10(3), 12(2) and 19(2)

INFORMATION REQUIRED IN RESPECT OF PERSONS SEEKING TO CARRY ON, MANAGE OR WORK AT AN ESTABLISHMENT OR AGENCY

1. Positive proof of identity including a recent photograph.
2. Either—
 - (a) where the certificate is required for a purpose relating to section 115(5)(ea) of the Police Act 1997 (registration under Part II of the Care Standards Act 2000)(**29**), or the position falls within section 115(3) or (4) of that Act(**30**), an enhanced criminal record certificate issued under section 115 of that Act; or
 - (b) in any other case, a criminal record certificate issued under section 113 of that Act, including, where applicable, the matters specified in section 113(3A) or (3C) or 115(6A) or (6B) of that Act(**31**).
3. Two written references, being references from the person's most recent employers, if any.

(29) Section 115(5)(ea) is inserted by the Care Standards Act 2000, section 104, on a date to be appointed. Sections 113 and 115, as amended, have not yet been brought into force.

(30) A position is within section 115(3) if it involves regularly caring for, training, supervising or being in sole charge of persons aged under 18. A position is within section 115(4) if it is of a kind specified in regulations and involves regularly caring for, training, supervising or being in sole charge of persons aged 18 or over.

(31) Sections 113(3A) and 115(6A) are added to the Police Act 1997 by section 8 of the Protection of Children Act 1999 c. 14 on a date to be appointed, and amended by section 104 and 116 of, and paragraph 25 of Schedule 4 to, the Care Standards Act 2000. Sections 113(3C) and 115(6B) are added to the Police Act 1997 by section 90 of the Care Standards Act 2000 on a date to be appointed.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

4. Where a person has previously worked in a position which involved work with children or vulnerable adults, verification, so far as reasonably practicable, of the reason why he ceased to work in that position.
5. Documentary evidence of any relevant qualifications.
6. A full employment history, together with a satisfactory written explanation of any gaps in employment.
7. Where he is a health care professional, details of his registration with the body (if any) responsible for regulation of members of the health care profession in question.
8. Details of any criminal offences—
 - (a) of which the person has been convicted, including details of any convictions which are spent within the meaning of section 1 of the Rehabilitation of Offenders Act 1974⁽³²⁾ and which may be disclosed by virtue of the Rehabilitation of Offenders (Exceptions) Order 1975⁽³³⁾; or
 - (b) in respect of which he has been cautioned by a constable and which, at the time the caution was given, he admitted.

SCHEDULE 3

Regulation 21(1), (3)

PART I

PERIOD FOR WHICH MEDICAL RECORDS MUST BE RETAINED

<i>Type of patient</i>	<i>Minimum period of retention</i>
(a) (a) Patient who was under the age of 17 at the date on which the treatment to which the records refer was concluded.	Until the patient's 25th birthday.
(b) (b) Patient who was aged 17 at the date on which the treatment to which the records refer was concluded.	Until the patient's 26th birthday.
(c) (c) Patient who died before attaining the age of 18.	A period of 8 years beginning on the date of the patient's death.
(d) (d) Patient who was treated for mental disorder during the period to which the records refer.	A period of 20 years beginning on the date of the last entry in the record.
(e) (e) Patient who was treated for mental disorder during the period to which the records refer and who died whilst receiving that treatment.	A period of 8 years beginning on the date of the patient's death.
(f) (f) Patient whose records relate to treatment by a general practitioner.	A period of 10 years beginning on the date of the last entry.

⁽³²⁾ 1974 c. 53.

⁽³³⁾ S.I. 1975/1023. Relevant amendments have been made by S.I. 1986/1249, S.I. 1986/2268 and S.I. 2001/1192.

<i>Type of patient</i>	<i>Minimum period of retention</i>
(g) (g) Patient who has received an organ transplant.	A period of 11 years beginning on the date of the patient's death or discharge whichever is the earlier.
(h) (h) All other cases.	A period of 8 years beginning on the date of the last entry in the record.

PART II

RECORDS TO BE MAINTAINED FOR INSPECTION

1. A register of patients, including—
 - (a) the name, address, telephone number, date of birth and marital status of each patient;
 - (b) the name, address and telephone number of the patient's next of kin or any person authorised by the patient to act on his behalf;
 - (c) the name, address and telephone number of the patient's general practitioner;
 - (d) where the patient is a child, the name and address of the school which he attends or attended before admission to an establishment;
 - (e) where a patient has been received into guardianship under the Mental Health Act 1983, the name, address and telephone number of the guardian;
 - (f) the name and address of any body which arranged the patient's admission or treatment;
 - (g) the date on which the patient was admitted to an establishment or first received treatment provided for the purposes of an establishment or agency;
 - (h) the nature of the treatment for which the patient was admitted or which he received;
 - (i) where the patient has been an in-patient in an independent hospital, the date of his discharge;
 - (j) if the patient has been transferred to a hospital (including a health service hospital), the date of the transfer, the reasons for it and the name of the hospital to which the patient was transferred;
 - (k) if the patient dies whilst in an establishment or during treatment provided for the purposes of an establishment or agency, the date, time and cause of his death.
2. A register of all surgical operations performed in an establishment or by an agency, including—
 - (a) the name of the patient on whom the operation was performed;
 - (b) the nature of the surgical procedure and the date on which it took place;
 - (c) the name of the medical practitioner or dentist by whom the operation was performed;
 - (d) the name of the anaesthetist in attendance;
 - (e) the name and signature of the person responsible for checking that all needles, swabs and equipment used during the operation have been recovered from the patient;
 - (f) details of all implanted medical devices, except where this would entail the disclosure of information contrary to the provisions of section 33(5) of the Human Fertilisation and Embryology Act 1990 (restrictions on disclosure of information).
3. A register of each occasion on which a technique or technology to which regulation 42 applies has been used; including—

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- (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; and
 - (c) the name of the person using it.
4. A register of all mechanical and technical equipment used for the purposes of treatment provided by the establishment or agency including—
- (a) the date of purchase of the equipment;
 - (b) the date of installation of the equipment;
 - (c) details of maintenance of the equipment and the dates on which maintenance work was carried out.
5. A register of all events which must be notified to the Commission in accordance with regulation 28.
6. A record of the rostered shifts for each employee and a record of the hours actually worked by each person.
7. A record of each person employed in or for the purposes of the establishment, or for the purposes of the agency and each medical practitioner to whom practising privileges have been granted, including—
- (a) his name and date of birth;
 - (b) details of his position in the establishment or agency;
 - (c) dates of employment; and
 - (d) in respect of a health care professional, details of his professional qualifications and registration with his professional regulatory body.

SCHEDULE 4

Regulation 40(5)(a)

PART I

DETAILS TO BE RECORDED IN RESPECT OF PATIENTS RECEIVING OBSTETRIC SERVICES

1. The date and time of delivery of each patient, the number of children born to the patient, the sex of each child and whether the birth was a live birth or a stillbirth.
2. The name and qualifications of the person who delivered the patient.
3. The date and time of any miscarriage occurring in the hospital.
4. The date on which any child born to a patient left the hospital.
5. If any child born to a patient died in the hospital, the date and time of death.

PART II

DETAILS TO BE RECORDED IN RESPECT OF A CHILD BORN IN AN INDEPENDENT HOSPITAL

1. Details of the weight and condition of the child at birth.
2. A daily statement of the child's health.
3. If any paediatric examination is carried out involving any of the following procedures—
 - (a) examination for congenital abnormalities including congenital dislocation of the hip;
 - (b) measurement of the circumference of the head of the child;
 - (c) measurement of the length of the child;
 - (d) screening for phenylketonuria,details of such examination and the result.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Care Standards Act 2000 (“the Act”), and apply to England only. Part I of the Act establishes, in relation to England, the National Care Standards Commission (“the Commission”) and Part II provides for the registration and inspection of establishments and agencies, including private and voluntary health care establishments and agencies, by the Commission. It also provides powers for regulations governing the conduct of establishments and agencies. The majority of Parts I and II of the Act (in so far as not already in force) will be brought into force on 1 April 2002.

Regulation 3 provides that “listed services” include treatment using the prescribed techniques and technology set out in regulation 3(1). Regulation 3(2) then excepts certain techniques and technology from being listed services, and regulation 3(2) excludes certain establishments from the definition of an independent hospital under section 2 of the Act. These include establishments providing medical or psychiatric treatment but which have no overnight beds for patients, establishments which are service hospitals under the Armed Forces Act 1981, or which are establishments catering for offenders under the Prison Act 1952. In addition, independent clinics (as defined in these Regulations) are excluded, as are establishments where general practitioners provide NHS services, but where there may be a small minority of private patients who also receive treatment. The private residence of a patient is also excluded provided that treatment is provided there only to that patient, as are surgeries and consulting rooms (which are separate from a hospital) which provide medical services under arrangements made on behalf of patients by their employers or others, and sports grounds and gymnasias where treatment is given to those taking part in sporting activities and events. Regulation 3(4) modifies the definition of cosmetic surgery for the purpose of section 2(7) of the Act. Regulation 4 defines the meaning of the term “independent clinic” and regulation 5 excepts certain establishments from being an independent medical agency.

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By regulation 6, each establishment or agency must have a statement of purpose consisting of the matters set out in Schedule 1, and a patients' guide to the establishment or agency. The establishment or agency must be carried on in a manner which is consistent with the statement of purpose.

Regulation 9 sets out the policies and procedures which must be prepared and implemented in relation to an establishment.

Regulations 10 to 14 make provision about the fitness of the persons carrying on and managing an establishment or agency and require satisfactory information to be obtained in relation to the matters prescribed in Schedule 2. Where the provider is an organisation, it must nominate a responsible individual in respect of whom this information must be available (regulation 10). Regulation 11 prescribes the circumstances where a manager must be appointed for the establishment or agency, and regulation 13 imposes general requirements in relation to the proper conduct of the establishment or agency, and the need for appropriate training.

Part III makes provision about the conduct of establishments or agencies, in particular about the quality of the services to be provided in an establishment or agency, including matters relating to privacy, dignity and religious observance, the staffing of the establishment or agency and the fitness of workers and about complaints and record keeping (regulation 21 and Schedule 3). Provision is also made about the suitability of premises and the fire precautions to be taken and the management of establishments and agencies. The registered provider is required to visit the establishment or agency as prescribed (regulation 26), and regulation 27 imposes requirements relating to the financial viability of the establishment or agency. Regulations 28 to 32 deal with the giving of notices to the Commission.

Part IV and Schedule 4 set out additional requirements that apply to independent hospitals, and Parts V and VI set out additional requirements applying to independent clinics and independent medical agencies.

Part VII deals with miscellaneous matters. In particular, regulation 51 provides for offences. A breach of regulations 6, 7, 9, 14, 15, 16(1) to (4), 17 to 32, 34 to 42 and 44 to 49 may found an offence on the part of the registered person. However, no prosecution may be brought unless the Commission has given the registered person a notice which sets out in what respect it is alleged he is not complying with a regulation, and what action, and by when, the Commission considers is necessary in order to comply with the regulation.