
STATUTORY INSTRUMENTS

2001 No. 3968

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

**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(1);

“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(2), 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(3); 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(4) 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(5);

“medical practitioner” means a registered medical practitioner(6);

(1) 1984 c. 24.

(2) 1983 c. 20.

(3) 1997 c. 46.

(4) 1999 c. 8.

(5) S.I.1994/3017.

(6) 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.

“midwife” means a registered midwife(7) 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(8);

“the NHS Act” means the National Health Service Act 1977(9);

“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(10).

(2) In these Regulations, a reference—

- (a) to a numbered regulation or Schedule is to the regulation in, or Schedule to, these Regulations bearing that number;
- (b) in a regulation or Schedule to a numbered paragraph, is to the paragraph in that regulation or Schedule bearing that number;
- (c) in a paragraph to a lettered or numbered sub-paragraph is to the sub-paragraph in that paragraph bearing that letter or number.

(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)(11);
- (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

(7) 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.

(8) 1997 c. 24.

(9) 1977 c. 49.

(10) See section 2(7).

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

- 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⁽¹²⁾ or regulation 8 or 12 of the Work in Compressed Air Regulations 1996⁽¹³⁾; 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⁽¹⁴⁾.
- (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;
 - (b) an establishment which is a service hospital within the meaning of section 13(9) of the Armed Forces Act 1981⁽¹⁵⁾;
 - (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⁽¹⁶⁾;
 - (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;

⁽¹²⁾ S.I. 1997/2776.

⁽¹³⁾ S.I. 1996/1656.

⁽¹⁴⁾ 1990 c. 37.

⁽¹⁵⁾ 1981 c. 55.

⁽¹⁶⁾ 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.

- (g) sports grounds and gymnasias 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 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.