

SCHEDULE 1

Regulation 3

Regulated Activities

Personal care

1.—(1) Subject to sub-paragraphs (2) and (3), the provision of personal care for persons who, by reason of old age, illness or disability are unable to provide it for themselves, and which is provided in a place where those persons are living at the time the care is provided.

(2) This paragraph does not apply where paragraph 2 (accommodation for persons who require nursing or personal care) or paragraph 4 (accommodation and nursing or personal care in the further education sector) applies.

(3) The following types of provision are excepted from sub-paragraph (1)—

- (a) the supply of carers to a service provider by an undertaking acting as an employment agency or employment business for the purposes of that provider carrying on a regulated activity;
- (b) the introduction of carers to an individual (other than a service provider) by a person (including an employment agency or an employment business) having no ongoing role in the direction or control of the service provided to that individual;
- (c) the services of a carer employed by an individual, without the involvement of an undertaking acting as an employment agency or employment business, and working wholly under the direction and control of that individual in order to meet that individual's own care requirements; and
- (d) the provision of personal care by a person managing a prison or other similar custodial establishment (other than a hospital within the meaning of Part 2 of the 1983 Act).

(4) In sub-paragraph (3), “carer” means an individual who provides personal care to a person referred to in sub-paragraph (1).

Accommodation for persons who require nursing or personal care

2.—(1) The provision of residential accommodation, together with nursing or personal care.

(2) Sub-paragraph (1) does not apply to the provision of accommodation—

- (a) to an individual by an adult placement carer under the terms of a carer agreement;
- (b) in a school; or
- (c) in an institution within the further education sector.

Accommodation for persons who require treatment for substance misuse

3. The provision of residential accommodation for a person, together with treatment for drug or alcohol misuse, where acceptance by the person of such treatment is a condition of the provision of the accommodation.

Accommodation and nursing or personal care in the further education sector

4.—(1) Subject to sub-paragraph (2), the provision of residential accommodation together with nursing or personal care for persons in an institution within the further education sector.

(2) Sub-paragraph (1) only applies where the number of persons to whom nursing or personal care and accommodation are provided is more than one tenth of the number of students to whom both education and accommodation are provided.

Treatment of disease, disorder or injury

5.—(1) Subject to sub-paragraph (2), the provision of treatment for a disease, disorder or injury by or under the supervision of—

- (a) a health care professional, or a multi-disciplinary team which includes a health care professional; or
- (b) a social worker, or a multi-disciplinary team which includes a social worker, where the treatment is for a mental disorder.

(2) The activities set out in sub-paragraph (3) are excepted from sub-paragraph (1).

(3) The activities referred to sub-paragraph (2) are—

- (a) assessment or medical treatment for persons detained under the 1983 Act;
- (b) the provision of treatment by means of surgical procedures;
- (c) diagnostic and screening procedures;
- (d) services in slimming clinics;
- (e) the practice of alternative and complementary medicine, with the exception of the practice of osteopathy or chiropractic;
- (f) the provision of treatment in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of persons taking part in, or attending, sporting activities and events;
- (g) the provision of treatment (not being first aid for the purposes of paragraph 14 of Schedule 2) under temporary arrangements to deliver health care to those taking part in, or attending, sporting or cultural events;
- (h) the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where the primary use of that chamber is—
 - (i) pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997⁽¹⁾ or regulation 8 or 12 of the Work in Compressed Air Regulations 1996⁽²⁾, or
 - (ii) otherwise for the treatment of workers in connection with the work which they perform; and
- (i) the carrying on of any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990⁽³⁾.

(4) In this paragraph—

- (a) “health care professional” means a person who is—
 - (i) a medical practitioner,
 - (ii) a dental practitioner,
 - (iii) a dental hygienist,
 - (iv) a dental therapist,
 - (v) a dental nurse,
 - (vi) a dental technician,
 - (vii) an orthodontic therapist,

(1) [S.I. 1997/2776](#).

(2) [S.I. 1996/1656](#).

(3) [1990 c. 37](#). Paragraph 1 of Schedule 2 was amended by the Human Fertilisation and Embryology Act 2008 ([c. 22](#)), Schedule 2, paragraph 2 and Schedule 8, Part I and by [S.I. 2007/1522](#).

- (viii) a nurse,
- (ix) a midwife,
- (x) a biomedical scientist,
- (xi) a clinical scientist,
- (xii) an operating department practitioner,
- (xiii) a paramedic, or
- (xiv) a radiographer;
- (b) “biomedical scientist”, “clinical scientist”, “operating department practitioner”, “paramedic” and “radiographer” mean persons registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order⁽⁴⁾;
- (c) “dental practitioner” means a dentist registered as such with the General Dental Council pursuant to section 14 of the Dentists Act 1984⁽⁵⁾;
- (d) “dental hygienist”, “dental therapist”, “dental nurse”, “dental technician” and “orthodontic therapist” mean persons registered as such with the General Dental Council in the dental care professionals register⁽⁶⁾;
- (e) “mental disorder” means any disorder or disability of the mind, including dependence on alcohol or drugs;
- (f) “midwife” means a registered midwife;
- (g) “social worker” means a person who is registered as such with the General Social Care Council pursuant to section 56(1)(a) of the Care Standards Act 2000⁽⁷⁾.

Assessment or medical treatment for persons detained under the 1983 Act

6.—(1) The assessment of, or medical treatment (other than surgical procedures) for, a mental disorder affecting a person in a hospital where that person is—

- (a) detained in that hospital pursuant to the provisions of the 1983 Act (with the exception of section 135 or 136⁽⁸⁾);
 - (b) recalled to that hospital under section 17E of that Act⁽⁹⁾; or
 - (c) detained in that hospital pursuant to an order or direction made under another enactment, where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.
- (2) In this paragraph—
- (a) “hospital” means a hospital within the meaning of Part 2 of that Act⁽¹⁰⁾;

(4) “Relevant professions” are set out in Schedule 3, paragraph 1 of the 2001 Order. See *S.I. 2004/2033*, articles 3(4)(c) and 10(5)(b)(ii) and *S.I. 2007/3101*, Part 21, for relevant amendments.

(5) Section 14 of the Dentists Act 1984 (c.24) (“the 1984 Act”) was substituted by the Dentists Act 1984 (Amendment) Order 2005 (*S.I. 2005/2011*) (“the 2005 Order”), article 2(6) and amended by *S.I. 2007/3101*, regulation 111.

(6) The dental care professionals register was established by section 36B of the 1984 Act as inserted by article 29 of the 2005 Order and amended by *S.I. 2001/3101*, regulation 122.

(7) 2000 c.14. See also *S.I. 2007/3101*, regulations 230 and 232(a) for relevant amendments.

(8) Section 135 was amended by the Mental Health (Scotland) Act 1984 (c.36) Schedule 3, paragraph 56, the Police and Criminal Evidence Act 1984 (c.60) Schedule 6, Part 1 and Schedule 7, Part 1, the National Health Service and Community Care Act 1990 (c.19) Schedule 10, the Care Standards Act 2000 (c.14) Schedule 4, paragraph 9, the Mental Health Act 2007 (“the 2007 Act”) (c.12) section 44 and Schedule 2, paragraph 10(a) and *S.I. 2005/2078*, Schedule 1, paragraph 2(9). Section 136 was amended by the 2007 Act, section 44 and Schedule 2, paragraph 10(b).

(9) Section 17E was inserted by section 32 of the 2007 Act.

(10) See sections 34(2) and 145(1) of the 1983 Act; relevant amendments were made by the Care Standards Act 2000, Schedule 4, paragraph 9.

- (b) “medical treatment” has the same meaning as in section 145 of that Act⁽¹¹⁾; and
- (c) “mental disorder” has the same meaning as in section 1 of that Act⁽¹²⁾.

Surgical procedures

7.—(1) Subject to sub-paragraphs (2) to (5), surgical procedures (including all pre-operative and post-operative care associated with such procedures) carried on by a health care professional for—

- (a) the purpose of treating disease, disorder or injury;
 - (b) cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body; or
 - (c) the purpose of religious observance.
- (2) Subject to sub-paragraph (3), the following procedures are excepted from sub-paragraph (1)—
- (a) nail surgery and nail bed procedures carried out by a health care professional on any area of the foot; and
 - (b) surgical procedures involving the curettage, cautery or cryocautery of warts, verrucae or other skin lesions carried out by—
 - (i) a medical practitioner, or
 - (ii) another health care professional on any area of the foot.
- (3) Sub-paragraph (2) only applies where the procedures are carried out—
- (a) without anaesthesia; or
 - (b) using local anaesthesia.
- (4) The following cosmetic procedures are excepted from sub-paragraph (1)(b)—
- (a) the piercing of any part of the human body;
 - (b) tattooing;
 - (c) the subcutaneous injection of a substance or substances for the purpose of enhancing a person’s appearance; and
 - (d) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.

Diagnostic and screening procedures

- 8.—(1) Subject to sub-paragraph (3), diagnostic and screening procedures involving—
- (a) the use of X-rays and other methods in order to examine the body by the use of radiation, ultrasound or magnetic resonance imaging;
 - (b) the use of instruments or equipment which are inserted into the body to—
 - (i) view its internal parts, or
 - (ii) gather physiological data;
 - (c) the removal of tissues, cells or fluids from the body for the purposes of discovering the presence, cause or extent of disease, disorder or injury;
 - (d) the use of equipment in order to examine cells, tissues and other bodily fluids for the purposes of obtaining information on the causes and extent of a disease, disorder or injury; and

⁽¹¹⁾ Section 145 was amended by section 7 of the 2007 Act.

⁽¹²⁾ Section 1 was amended by section 1(2) of the 2007 Act.

(e) the use of equipment to measure or monitor physiological data in relation to the—

- (i) audio-vestibular system,
- (ii) vision system,
- (iii) neurological system,
- (iv) cardiovascular system,
- (v) respiratory system,
- (vi) gastro-intestinal system, or
- (vii) urinary system,

for the purposes of obtaining information on the causes and extent of a disease, disorder or injury, or the response to a therapeutic intervention, where such information is needed for the purposes of the planning and delivery of care or treatment.

(2) Subject to sub-paragraph (3), the analysis and reporting of the results of the procedures referred to in sub-paragraph (1).

(3) The procedures specified in sub-paragraph (4), and the analysis and reporting of the results of those procedures, are excepted from sub-paragraphs (1) and (2).

(4) The procedures referred to in sub-paragraph (3) are—

- (a) the taking of blood samples where—
 - (i) the procedure is carried out by means of a pin prick, and
 - (ii) it is not necessary to send such samples for analysis to a place which is established for the purposes of carrying out tests or research in relation to samples of bodily cells, tissues or fluids;
- (b) the taking and analysis of samples of bodily tissues, cells or fluids in order to ascertain—
 - (i) the existence of a genetically inherited disease or disorder, or
 - (ii) the influence of an individual's genetic variation on drug response,where such procedures are part of neither the planning and delivery of care or treatment nor a national screening programme, other than for cancer;
- (c) the carrying out of procedures as part of a national cancer screening programme by a body established solely for the purpose of such a programme;
- (d) fitness screening procedures carried out in a gymnasium in order to ascertain that a person is sufficiently healthy to use fitness equipment or take part in fitness routines safely;
- (e) the taking of X-rays by chiropractors;
- (f) the use of ultrasound equipment by physiotherapists; and
- (g) the use of an auroscope.

(5) For the purposes of this paragraph—

- (a) “chiropractor” means a person registered with the General Chiropractic Council pursuant to section 3, 4, 5 or 5A of the Chiropractors Act 1994⁽¹³⁾; and
- (b) “physiotherapist” means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order.

Management of supply of blood and blood derived products etc.

9. The management of—

(13) 1994 c. 17. Section 5A was inserted by S.I. 2007/3101, regulation 219.

- (a) the supply of blood, blood components and blood derived products intended for transfusion;
- (b) the supply of tissues and tissue derived products intended for transplant, grafting or use in a surgical procedure; and
- (c) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.

Transport services, triage and medical advice provided remotely

10.—(1) Transport services provided by an English NHS provider⁽¹⁴⁾ by means of a vehicle which is designed for the primary purpose of carrying a person who requires treatment.

(2) Medical advice in cases where immediate action or attention is needed, or triage provided, over the telephone or by electronic mail by a body established for that purpose.

(3) For the purposes of this paragraph—

- (a) “triage” means the assignment of degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment of service users; and
- (b) “vehicle” includes an air or water ambulance.

Maternity and midwifery services

11.—(1) Subject to sub-paragraph (2), maternity and midwifery services carried on by, or under the supervision of, a health care professional.

(2) The following services are excepted from sub-paragraph (1)—

- (a) midwifery services, where the provision of those services is carried on by an individual—
 - (i) acting on their own behalf,
 - (ii) otherwise than in pursuance of the 2006 Act, and
 - (iii) who provides such services only to service users in their own homes;
- (b) the provision of advice, information and support in relation to pregnancy, childbirth or the acquisition of parenting skills, where provided by a body whose primary purpose or function is not the provision of health care (other than that advice, information and support);
- (c) services provided under arrangements relating to the care of pregnant women and women who are breast feeding made pursuant to section 254 of, and Schedule 20 to, the 2006 Act (local social services authorities).

Termination of pregnancies

12. The termination of pregnancies.

Services in slimming clinics

13. Services provided in a slimming clinic consisting of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction.

⁽¹⁴⁾ See section 97(1) of the Act for the definition of “English NHS provider”. See regulation 3(6) which provides that the words “by an English NHS provider” cease to have effect on 1st April 2011.

Nursing care

14.—(1) Subject to sub-paragraph (2), the provision of nursing care, including nursing care provided in a person’s own home which is not—

- (a) provided as part of any other regulated activity; and
- (b) exempted from being a regulated activity under any other paragraph in this Schedule.

(2) The following types of provision are excepted from sub-paragraph (1)—

- (a) the supply of nurses to a service provider by an undertaking acting as an employment agency or employment business for the purposes of that provider carrying on a regulated activity;
- (b) the introduction of nurses to an individual (other than a service provider) by a person (including an employment agency or an employment business) having no ongoing role in the direction or control of the service provided to that individual; and
- (c) the services of a nurse employed by an individual, without the involvement of an undertaking acting as an employment agency or an employment business, and working wholly under the direction and control of that individual in order to meet that individual’s own nursing requirements.

Family planning services

15. The insertion or removal of an intrauterine contraceptive device carried out by, or under the supervision of, a health care professional.

SCHEDULE 2

Regulations 3(7) and (8)

Regulated Activities: General exceptions

1.—(1) Any activity which is carried on—

- (a) in the course of a family or personal relationship; and
- (b) for no commercial consideration.

(2) A family relationship includes a relationship between two persons who—

- (a) live in the same household; and
- (b) treat each other as though they were members of the same family.

(3) A personal relationship is a relationship between or among friends.

(4) A friend of a person (A) includes a person who is a friend of a member of A’s family.

2. Any activity which involves the carrying on of an establishment or agency within the meaning of the Care Standards Act 2000⁽¹⁵⁾ for which Her Majesty’s Chief Inspector of Education, Children’s Services and Skills is the registration authority under that Act.

3. The provision of all medical services (including medical services provided otherwise than under the 2006 Act) by a provider whose sole or main purpose is the provision of primary medical services—

- (a) under arrangements made pursuant to the following sections of the 2006 Act—
 - (i) section 3 (Secretary of State’s duty as to provision of certain services),

(15) 2000 c.14.

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- (ii) section 83(2)(b) (primary medical services),
 - (iii) section 92 (arrangements by Strategic Health Authorities for the provision of primary medical services); or
- (b) under a contract entered into pursuant to section 84 of that Act (general medical services contracts: introductory)(**16**).
4. Subject to paragraph 5, and except where paragraph 3 applies, the provision of treatment in a surgery or consulting room otherwise than under arrangements made pursuant to the 2006 Act by—
- (a) an individual medical practitioner who also provides services (whether there or elsewhere) under arrangements made pursuant to the 2006 Act; or
 - (b) a group of medical practitioners all of whom also provide services (whether there or elsewhere) under arrangements made pursuant to the 2006 Act.
5. Paragraph 4 does not apply in relation to—
- (a) treatment carried out under anaesthesia or intravenously administered sedation;
 - (b) dental treatment carried out under general anaesthesia;
 - (c) obstetric services and, in connection with childbirth, medical services;
 - (d) the termination of pregnancies;
 - (e) cosmetic surgery, with the exception of the procedures referred to in paragraph 7(4) of Schedule 1;
 - (f) haemodialysis or peritoneal dialysis;
 - (g) endoscopy; or
 - (h) the provision of hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a person who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the supervision or direction of a medical practitioner.
6. The provision by a general medical practitioner (other than one who is a provider for the purposes of paragraph 3) of—
- (a) primary medical services under arrangements made pursuant to the sections of the 2006 Act referred to in paragraph 3(a) and (b); or
 - (b) any of the services listed in paragraph 5 in premises which are the premises used by that practitioner for the purpose of the provision of primary medical services under the 2006 Act(**17**).
7. The provision of services (other than in a surgery, consulting room or hospital) involving treatment by medical practitioners working for the purposes of an undertaking which also provides such services in pursuance of the 2006 Act(**18**).
8. Medical services provided (otherwise than in a hospital) only under arrangements made on behalf of service users by—
- (a) their employer;
 - (b) a government department; or
 - (c) an insurance provider with whom the service users hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity.

(16) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

(17) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

(18) This paragraph will cease to have effect on 1st April 2012: see regulation 3(8)(a).

9. Treatment provided in a vehicle which is operated by an ambulance provider which is not an English NHS body⁽¹⁹⁾.

10. Forensic medical services provided under arrangements made with a police authority as defined in section 101 (interpretation) of the Police Act 1996⁽²⁰⁾.

11. Dental services—

(a) provided as primary dental services in pursuance of Part 5 of the 2006 Act, except where those services are provided—

(i) by a Primary Care Trust under section 99(2) (primary dental services) of that Act, or

(ii) by an NHS trust or NHS foundation trust; or

(b) of a kind which, if provided in pursuance of that Act, would be provided as primary dental services under Part 5, except where those services are provided in a hospital⁽²¹⁾.

12. Primary ophthalmic services provided under Part 6 of the 2006 Act and services of a kind which, if provided in pursuance of that Act, would be provided as primary ophthalmic services under that Part.

13. Pharmaceutical services and local pharmaceutical services provided under Part 7 of the 2006 Act and services of a kind which, if provided in pursuance of that Act, would be provided as pharmaceutical services or local pharmaceutical services under that Part.

14. The provision of first aid by—

(a) health care professionals where it is provided in unexpected or potentially dangerous situations requiring immediate action;

(b) organisations established for that purpose; or

(c) non-health care professionals trained to deliver such treatment.

15. Defence medical and dental services being—

(a) health or dental care provided by the Armed Services;

(b) education and training provided by the Armed Services to service and other personnel in connection with the provision of health or dental care, including the maintenance of the clinical skills of such personnel; and

(c) any service or facility falling within sub-paragraph (a) or (b) provided on behalf of the Armed Services under any agreement or arrangement made with the Armed Services.

16. Treatment provided in a school to the pupils of that school by a nurse who is engaged and directed by the school.

17. In this Schedule—

(a) “insurance provider” means—

(i) a person regulated by the Financial Services Authority who sells insurance, or underwrites the risk of such insurance, or

(ii) the agent of such a person; and

(b) “primary dental services” includes the provision of dental implants.

⁽¹⁹⁾ This paragraph will cease to have effect on 1st April 2011: *see* regulation 3(8)(b).

⁽²⁰⁾ 1996 c.16. The definition of police authority in section 101 was amended by the Greater London Authority Act 1999 (c. 29), section 312(2).

⁽²¹⁾ This paragraph will cease to have effect on 1st April 2011: *see* regulation 3(8)(b).

SCHEDULE 3

Regulations 4, 5, 6 and 21

Information Required In Respect Of Persons Seeking To Carry On,
Manage Or Work For The Purposes Of Carrying On, A Regulated Activity

1. Proof of identity including a recent photograph.
2. Where the certificate is required for a purpose referred to in—
 - (a) section 113A(2)(b) of the Police Act 1997(22), a criminal record certificate issued under section 113A of that Act together with, after the appointed day and where applicable, relevant information relating to children or vulnerable adults; or
 - (b) section 113B(2)(b) of the Police Act 1997, an enhanced criminal record certificate issued under section 113B of that Act together with, where applicable, suitability information relating to children or vulnerable adults.
3. Satisfactory evidence of conduct in previous employment concerned with the provision of services relating to—
 - (a) health or social care; or
 - (b) children or vulnerable adults.
4. Where a person (P) has been previously employed in a position whose duties involved work with children or vulnerable adults, satisfactory verification, so far as reasonably practicable, of the reason why P's employment in that position ended.
5. Satisfactory documentary evidence of any relevant qualification.
6. A full employment history, together with a satisfactory written explanation of any gaps in employment.
7. Satisfactory information about any physical or mental health conditions which are relevant to the person's ability to carry on, manage or work for the purposes of, the regulated activity.
8. For the purposes of this Schedule—
 - (a) "the appointed day" means the day on which section 30 of the Safeguarding Vulnerable Groups Act 2006(23) comes into force;
 - (b) "relevant information relating to children or vulnerable adults" has the same meaning as in section 31(2) and (3) of that Act;
 - (c) "satisfactory" means satisfactory in the opinion of the Commission; and
 - (d) "suitability information relating to children or vulnerable adults" means the information specified in sections 113BA and 113BB respectively of the Police Act 1997(24).

(22) 1997 c. 50. Sections 113A and 113B were inserted by the Serious Organised Crime and Police Act 2005 (c. 15), section 163(2), and amended by the Safeguarding Vulnerable Groups Act 2006 (c. 47), Schedule 9, Part 2, paragraphs 14(1), (2) and (3).

(23) 2006 c.47.

(24) Sections 113BA and 113BB were inserted into the Police Act 1997 by the Safeguarding Vulnerable Groups Act 2006, section 63(1), Schedule 9, Part 2, paragraph 14(1) and (4).

SCHEDULE 4

Regulation 28

Fixed Penalty Offences

| <i>Provision creating offence</i> | <i>General nature of offence</i> | <i>Monetary amount of penalty</i> |
|--------------------------------------|---|---|
| Regulation 27 of these Regulations | Contravention of, or failure to comply with, requirements relating to quality and safety of service provision in relation to a regulated activity | £4,000 in the case of an offence committed by a service provider; £2,000 in the case of an offence committed by a registered manager |
| Section 10(1) of the Act | Carrying on a regulated activity without being registered | £4,000 |
| Section 33 of the Act | Failure to comply with conditions | £4,000 in the case of an offence committed by a service provider; £2,000 in the case of an offence committed by a registered manager |
| Section 34(1) of the Act | Carrying on a regulated activity whilst registration is suspended | £4,000 |
| Section 34(2), (3) or (4) of the Act | Managing a regulated activity whilst registration is cancelled or suspended | £2,000 |
| Section 63(7) of the Act | Obstructing entry and inspection | £300 |
| Section 64(4) of the Act | Failure to provide documents and information | £300 |
| Section 65(4) of the Act | Failure to provide an explanation | £300 |