Draft Regulations laid before Parliament under section 162(3) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.
These draft Regulations supersede draft S.I. 9780111487006 (the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009) and are being issued free of charge to all known recipients of that draft instrument

DRAFT STATUTORY INSTRUMENTS

2010 No. XXXX

NATIONAL HEALTH SERVICE, ENGLAND
SOCIAL CARE, ENGLAND
PUBLIC HEALTH, ENGLAND

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Made - - - -	*000*
Coming into force - -	*1st April 2010*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 8(1), 20(1) to (5), 35, 86(2) and (4), 87(1) and (2) and 161(3) and (4) of the Health and Social Care Act 2008(**1**).

In accordance with section 20(8) of the Act, the Secretary of State has consulted such persons as he considers appropriate.

A draft of these Regulations was laid before Parliament in accordance with section 162(3) of the Health and Social Care Act 2008 and approved by resolution of each House of Parliament.

PART 1

GENERAL

Citation and commencement

1. These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and come into force on 1st April 2010.

(**1**) 2008 c. 14. "Prescribed" and "regulations" are defined in section 97(1) of the Act.

Interpretation

2. In these Regulations—

"the Act" means the Health and Social Care Act 2008;

"the 1983 Act" means the Mental Health Act 1983(**2**);

"the 2006 Act" means the National Health Service Act 2006(**3**);

"the 2001 Order" means the Health Professions Order 2001(**4**);

"adult placement carer" means an individual who, under the terms of a carer agreement, provides, or intends to provide, personal care for service users together with, where necessary, accommodation in the individual's home;

"adult placement scheme" means a scheme carried on (whether or not for profit) by a local authority or other person for the purposes of—

(a) recruiting and training adult placement carers;

(b) making arrangements for the placing of service users with adult placement carers; and

(c) supporting and monitoring placements;

"carer agreement" means an agreement entered into between a person carrying on an adult placement scheme and an individual for the provision, by that individual, of personal care to a service user together with, where necessary, accommodation in the individual's home;

"chiropodist or podiatrist" means a person registered as such with the Health Professions Council pursuant to article 5 of the 2001 Order(**5**);

"employment" means—

(a) employment under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract (including under a carer agreement); and

(b) the grant of practising privileges,

and "employed" and "employer" should be construed accordingly;

"employment agency" and "employment business" have the same meanings as in the Employment Agencies Act 1973(**6**);

"health care professional" means, except in paragraph 5 of Schedule 1, a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(**7**) applies;

"hospital", except in paragraphs 1(3)(d) and 6 of Schedule 1, has the same meaning as in section 275 of the 2006 Act;

"institution within the further education sector" has the same meaning as in section 91 of the Further and Higher Education Act 1992(**8**);

"local anaesthesia" means any anaesthesia other than general, spinal or epidural anaesthesia, and also excludes the administration of a regional nerve block;

(**2**) 1983 c.20.
(**3**) 2006 c.41.
(**4**) S.I. 2002/254.
(**5**) *See* the definition of "relevant professions" in Schedule 3, paragraph 1 of the 2001 Order as amended by S.I. 2004/2033, article 10(5)(b)(i).
(**6**) 1973 c.35. See section 13(2) and (3). Section 13(2) was amended by the Employment Relations Act 1999 (c.26), Schedule 7, paragraphs 1 and 7.
(**7**) 1999 c.8. Section 60(2) was amended by the Health and Social Care Act 2008, Schedule 8, paragraph 1(3) and Schedule 15, Part 2 and by S.I. 2002/253 and the 2001 Order.
(**8**) 1992 c.13.

"medical practitioner" means a registered medical practitioner(**9**);

"nominated individual" must be construed in accordance with regulation 5(2);

"nurse" means a registered nurse;

"nursing care" means any services provided by a nurse and involving—

(a) the provision of care; or

(b) the planning, supervision or delegation of the provision of care,

other than any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a nurse;

"personal care" means—

(a) physical assistance given to a person in connection with—

(i) eating or drinking (including the administration of parenteral nutrition),

(ii) toileting (including in relation to the process of menstruation),

(iii) washing or bathing,

(iv) dressing,

(v) oral care, or

(vi) the care of skin, hair and nails (with the exception of nail care provided by a chiropodist or podiatrist); or

(b) the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a), where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision;

"practising privileges" means the grant, by a person managing a hospital, to a medical practitioner of permission to practise as a medical practitioner in that hospital;

"premises" means—

(a) any building or other structure, including any machinery or engineering systems which are physically affixed and integral to such building or structure; or

(b) a vehicle;

"registered manager" means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a manager in respect of that activity, and "manage" should be construed accordingly;

"registered person" means, in respect of a regulated activity, a person who is the service provider or registered manager in respect of that activity;

"school" has the same meaning as in the Education Act 1996(**10**);

"service provider" means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider in respect of that activity;

"service user" means a person who receives services provided in the carrying on of a regulated activity;

"treatment", except in paragraph 6 of Schedule 1, includes—

(a) a diagnostic or screening procedure carried out for medical purposes;

(**9**) The definition of "registered medical practitioner" in Schedule 1 to the Interpretation Act 1978 (c.30) has been substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.

(**10**) 1996 c.56; *see* section 4 for the meaning of "school". Section 4 has been amended by the Education Act 1997 (c. 44), sections 51, 57(1) and (4) and Schedule 7, paragraphs 10(a) and (b) and Schedule 8, by the Education Act 2002 (c. 32), section 215(2) and Schedule 22, Part 3, and by the Childcare Act 2006 (c. 21), section 95(1), (2) and (3).

(b) the ongoing assessment of a service user's mental or physical state;

(c) nursing, personal and palliative care; and

(d) the giving of vaccinations and immunisations;

"vulnerable adult" has the same meaning as in section 59 of the Safeguarding Vulnerable Groups Act 2006(**11**).

PART 2

REGULATED ACTIVITIES

Prescribed activities

3.—(1) Subject to paragraphs (3) to (8), for the purposes of section 8(1) of the Act, the activities specified in Schedule 1 are prescribed as regulated activities.

(2) An activity which is ancillary to, or is carried on wholly or mainly in relation to, a regulated activity shall be treated as part of that activity.

(3) Subject to paragraph (4), until 1st October 2010, an activity is only a regulated activity if it is carried on by an English NHS body(**12**).

(4) Where services involving, or connected with, the provision of social care are provided by an English NHS body which is registered as an establishment or agency under Part 2 of the Care Standards Act 2000(**13**) in relation to the provision of those services then, to the extent that those services are capable of being a regulated activity for the purposes of these Regulations, they are only a regulated activity with effect from 1st October 2010.

(5) An activity is only a regulated activity if it is carried on in England.

(6) In Schedule 1, in paragraph 10(1), the words "by an English NHS provider" shall cease to have effect on 1st April 2011.

(7) Subject to paragraph (8), the activities specified in Schedule 2 are not regulated activities.

(8) In Schedule 2—

(a) paragraphs 3, 6 and 7 and, in paragraph 4, the words "and except where paragraph 3 applies", shall cease to have effect on 1st April 2012; and

(b) paragraphs 9 and 11 shall cease to have effect on 1st April 2011.

PART 3

REQUIREMENTS RELATING TO PERSONS CARRYING ON OR MANAGING A REGULATED ACTIVITY

Requirements where the service provider is an individual or partnership

4.—(1) This regulation applies where a service provider (P) is an individual or a partnership.

(2) P must not carry on a regulated activity unless P is fit to do so.

(3) P is not fit to carry on a regulated activity unless P is—

(**11**) 2006 c. 47. Section 59 was amended by S.I. 2008/912, Schedule 1, paragraph 21 and by the Education and Skills Act 2008 (c. 25), section 147(8).
(**12**) *See* section 97(1) of the Act for the definition of "English NHS body".
(**13**) 2000 c. 14.

(a) an individual who carries on the regulated activity, otherwise than in partnership with others, and satisfies the requirements set out in paragraph (4); or

(b) a partnership and each of the partners satisfies the requirements set out in paragraph (4);

(4) The requirements referred to are that P or, where applicable, each of the partners is—

(a) of good character;

(b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and

(c) able to supply to the Commission, or arrange for the availability of, information relating to themselves specified in Schedule 3.

Requirement where the service provider is a body other than a partnership

5.—(1) This regulation applies where the service provider is a body other than a partnership.

(2) The body must give notice to the Commission of the name, address and position in the body of an individual (in these Regulations referred to as "the nominated individual") who is employed as a director, manager or secretary of the body and who is responsible for supervising the management of the carrying on of the regulated activity by the body.

(3) The registered person must take all reasonable steps to ensure that the nominated individual is—

(a) of good character;

(b) physically and mentally fit to supervise the management of the carrying on of the regulated activity and has the necessary qualifications, skills and experience to do so; and

(c) able to supply to the registered person, or arrange for the availability of, the information specified in Schedule 3.

Requirements relating to registered managers

6.—(1) A person (M) shall not manage the carrying on of a regulated activity as a registered manager unless M is fit to do so.

(2) M is not fit to be a registered manager in respect of a regulated activity unless M is—

(a) of good character;

(b) physically and mentally fit to carry on the regulated activity and has the necessary qualifications, skills and experience to do so; and

(c) able to supply to the Commission, or arrange for the availability of, the information relating to themselves specified in Schedule 3.

Registered person: training

7.—(1) If the service provider is—

(a) an individual, the individual must undertake;

(b) a partnership, it must ensure that one of the partners undertakes; or

(c) a body other than a partnership, it must ensure that the nominated individual undertakes,

from time to time such training as is reasonably practicable and appropriate to ensure that there are the necessary experience and skills available for carrying on the regulated activity.

(2) The registered manager must undertake from time to time such training as is appropriate to ensure that the manager has the experience and skills necessary for managing the carrying on of the regulated activity.