Draft Regulations laid before Parliament under section 162(3)(b) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2014 No. 000

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

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 8, 20(1) to (5A), 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 that Act, the Secretary of State has consulted such persons as the Secretary of State 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 was approved by a resolution of each House of Parliament.

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

(2) This regulation and regulation 2 come into force on the day after the day on which these Regulations are made.

(**1**) 2008 c. 14. Section 20 of the Health and Social Care Act 2008 ("the 2008 Act") was amended by section 81 of the Care Act 2014 (c. 23). Section 161(3) of the 2008 Act was amended by section 294(4) of the Health and Social Care Act 2012 (c. 7).

(3) The provisions to which this paragraph applies come into force at the end of the period of 21 days beginning with the day on which these Regulations are made.

(4) Paragraph (3) applies to—

(a) regulation 5, and Schedule 3 insofar as it relates to regulation 5;

(b) regulation 20;

(c) regulation 21, only insofar as it relates to regulations 5 and 20;

(d) regulation 22(3);

(e) regulation 22(4), only insofar as it relates to a breach of regulation 20(2)(a) and (3);

(f) regulation 23(6);

(g) regulation 24 and Schedule 5, only insofar as they relate to a contravention of, or a failure to comply with, requirements in regulation 20(2)(a) and (3);

(h) regulation 26(2);

(i) Schedule 4.

(5) All other provisions of these Regulations come into force on 1st April 2015.

Interpretation

2.—(1) In these Regulations—

"16 to 19 Academy" has the same meaning as in section 1B of the Academies Act 2010(**2**);

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

"the 1983 Act" means the Mental Health Act 1983(**3**);

"the 2005 Act" means the Mental Capacity Act 2005(**4**);

"the 2006 Act" means the National Health Service Act 2006(**5**);

"the 2001 Order" means the Health and Social Work Professions Order 2001(**6**);

"the 2010 Regulations" means the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(**7**);

"employment" means—

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

(b) the grant of practising privileges by a service provider to a medical practitioner, giving permission to practice as a medical practitioner in a hospital managed by the service provider,

and "employed" and "employer" is to be construed accordingly;

"employment agency" and "employment business" have the same meaning as in section 13 (interpretation) of the Employment Agencies Act 1973(**8**);

"equipment" includes—

(**2**) 2010 c. 32. Section 1B was inserted by section 53(7) of the Education Act 2011 (c. 21).
(**3**) 1983 c. 20.
(**4**) 2005 c. 9. Relevant amendments were made by the Mental Health Act 2007 (c. 12), sections 50 and 55 and Part 10 of Schedule 11.
(**5**) 2006 c. 41.
(**6**) S.I. 2002/254. Relevant amendments were made by sections 213 and 214 of the Health and Social Care Act 2012 (c. 7) and S.I. 2004/2033, 2009/1182 and 2009/1357.
(**7**) S.I. 2010/781, as amended by S.I. 2011/2711, 2012/921, 2012/979, 2012/1479, 2012/1513, 2013/235 and 2013/472.
(**8**) 1973 c. 35. Relevant amendments were made by the Employment Relations Act 1999 (c. 26), section 31 and paragraphs 1 and 7 of Schedule7.

(a) a medical device (as defined in regulation 2(1) (interpretation) of the Medical Devices Regulations 2002)(**9**), and

(b) materials used in, or used by persons employed in, the carrying on of a regulated activity;

"health care professional", except in paragraph 4 of Schedule 1, means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(**10**) (regulation of health professions, social workers, other care workers, etc) applies;

"health service body" means—

(a) an NHS trust established under section 25 of the 2006 Act,

(b) an NHS foundation trust, or

(c) a Special Health Authority;

"hospital", except in paragraphs 1(3)(d) and 5 of Schedule 1, has the same meaning as in section 275 (interpretation) of the 2006 Act;

"institution within the further education sector" has the same meaning as in section 91 (interpretation of Education Acts) of the Further and Higher Education Act 1992(**11**);

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

"medical practitioner" means a registered medical practitioner;

"nominated individual" must be construed in accordance with regulation 6(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;

"partnership" does not include a limited liability partnership;

"personal care" means—

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

(i) eating or drinking (including the maintenance of established 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 person registered with the Health and Care Professions Council as a chiropodist or podiatrist pursuant to article 5 of the 2001 Order), 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

(**9**) S.I. 2002/618. Relevant amendments were made by S.I. 2008/2986.

(**10**) 1999 c. 21. Relevant amendments were made by the Health and Social Care Act 2008, sections 111 and 116, paragraph 1 of Schedule 8 and Part 2 of Schedule 15, the Health and Social Care Act 2012, sections 209 and 213, and S.I. 2002/253 and 2010/231.

(**11**) 1992 c. 13. Relevant amendments were made by the Apprenticeships, Skills, Children and Learning Act 2009 (c. 22), section 125 and paragraphs 1 and 13(1) and (2) of Schedule 8.

for themselves in relation to performing such an activity without such prompting and supervision;

"premises" means—

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

(b) a vehicle,

but in regulations 12, 14 and 15 does not include the service user's accommodation where such accommodation is not provided as part of the service user's care or treatment;

"reasonable adjustments" means such reasonable adjustments as would be required under the Equality Act 2010(**12**);

"registered manager" means, in respect of a regulated activity, a person registered with the Commission(**13**) under Chapter 2 of Part 1 of the Act as a manager in respect of that activity;

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

"relevant person", except in regulation 20, means the service user or, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf;

"school" has the same meaning as in section 4 of the Education Act 1996(**14**);

"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;

"shared lives agreement" means an agreement entered into between a person carrying on a shared lives 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;

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

"shared lives 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 shared lives carers,

(b) making arrangements for the placing of service users with shared lives carers, and

(c) supporting and monitoring placements;

"social worker" means a person who is registered as such in Part 16 of the register maintained by the Health and Care Professions Council under article 5 of the 2001 Order;

"treatment", except in paragraph 5 of Schedule 1, includes—

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

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

(c) nursing, personal and palliative care, and

(**12**) 2010 c. 15.
(**13**) By section 1(1) of the 2008 Act, "the Commission" means the Care Quality Commission.
(**14**) 1996 c. 56. Relevant amendments were made by the Education Act 1997 (c. 44), sections 51 and 57, paragraph 10 of Schedule 7 and Schedule 8, the Education Act 2002 (c. 32), section 215 and Part 3 of Schedule 22, the Childcare Act 2006 (c. 21), section 95, and the Education Act 2011 (c. 21), section 54 and paragraph 9 of Schedule 13, and S.I. 2010/1080.

(d) the giving of vaccinations and immunisations;

"vulnerable adult" has the same meaning as in section 60(1) (interpretation) of the Safeguarding Vulnerable Groups Act 2006(**15**).

(2) In the definition of "employment" in paragraph (1), the reference to otherwise than under a contract includes—

(a) under a shared lives agreement;

(b) under an agreement between the service provider and a temporary work agency for the supply of an agency worker to the service provider;

(c) under arrangements for persons to provide their services voluntarily.

(3) In paragraph (2)—

"agency worker" and "temporary work agency" have the same meaning as in the Agency Workers Regulations 2010(**16**).

PART 2

Regulated Activities

Prescribed activities

3.—(1) Subject to paragraphs (3) and (4), the activities specified in Schedule 1 are prescribed as regulated activities for the purposes of section 8(1) of the Act.

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

(4) The activities specified in Schedule 2 are not regulated activities.

PART 3

Requirements in relation to Regulated Activities

SECTION 1

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—

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

(i) paragraph (4), and

(ii) paragraph (5), or

(**15**) 2006 c. 47. Relevant amendments were made by section 65(2) of the Protection of Freedoms Act 2012 (c. 9).
(**16**) S.I. 2010/93. Relevant amendments were made by S.I. 2011/1941.