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.

DRAFT STATUTORY INSTRUMENTS

2012 No. 0000

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

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012

Made - - - - ***

Coming into force in accordance with regulation 1(2)

The Secretary of State for Health, in exercise of the powers conferred by sections 8(1), 20, 35 and 161(3) and (4) of the Health and Social Care Act 2008(**1**), makes the following Regulations:

In accordance with section 20(8) of the Health and Social Care Act 2008, 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 approved by a resolution of each House.

Citation and Commencement

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012.

(2) These Regulations shall come into force—

(a) on 18th June 2012 for all provisions except regulations 8(4) and 9(2) and (3);

(b) on 1st October 2012 for regulation 8(4);

(c) on 1st October 2013 for regulation 9(2) and (3).

Amendments to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

2. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(**2**) are amended as follows.

(**1**) 2008 c.14. "Prescribed" and "regulations" are defined in section 97(1).
(**2**) S.I. 2010/781, as amended by S.I. 2011/2711.

Amendment to regulation 4

3. In regulation 4 (requirements where the service provider is an individual or partnership)—

(a) for paragraph (3)(b), substitute—

"(b) a partnership and—

(i) each of the partners satisfies the requirements set out in paragraph (5); and

(ii) P satisfies the requirement set out in paragraph (6).";

(b) in paragraph (4), for "are that P or, where applicable, each of the partners" substitute "in paragraph 3(a) are that P"; and

(c) after paragraph (4), insert—

"(5) The requirements referred to in paragraph 3(b)(i) are that each of the partners is—

(a) of good character;

(b) physically and mentally fit to carry on the regulated activity; and

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

(6) The requirement referred to in paragraph 3(b)(ii) is that, through the combination of the qualifications, skills and experience of the partners, P has the necessary qualifications, skills and experience to carry on the regulated activity.".

Amendment to regulation 12

4. In regulation 12 (cleanliness and infection control), after paragraph (2), insert—

"(3) In this regulation, "medical device" has the same meaning as in regulation 2 (interpretation) of the Medical Devices Regulations 2002(**3**).".

Substitution of regulation 18

5. For regulation 18 (consent to care and treatment) substitute—

"**18.**—(1) In relation to the care and treatment provided for the service user, the registered person must have suitable arrangements in place for—

(a) obtaining, and acting in accordance with, the consent of service users, or the consent of another person who is able lawfully to consent to care and treatment on that service user's behalf; or

(b) where (a) does not apply, establishing, and acting in accordance with, the best interests of the service user.

(2) Section 4 of the Mental Capacity Act 2005(**4**) (best interests) applies for the purposes of this regulation as it applies for the purposes of that Act.".

Amendment to regulation 27

6. In regulation 27(4) (offences), for "took all reasonable steps or exercised all due diligence" substitute "took all reasonable steps and exercised all due diligence".

(**3**) S.I. 2002/618, as amended by S.I. 2008/2936.
(**4**) 2005 c.9.

Insertion of new Part 8: Review

7. After Part 7 (revocation) insert—

"PART 8

REVIEW

Review

30.—(1) Before 1st October 2017, the Secretary of State must—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.".

Amendments to Schedule 1

8.—(1) Schedule 1 (regulated activities) is amended as follows.

(2) In paragraph 1 (personal care)—

(a) for sub-paragraph (3)(c) substitute—

"(c) the services of a carer employed by an individual or related third party, 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 or related third party in order to meet the individual's own care requirements; and"; and

(b) in sub-paragraph (4), after the definition of "carer" insert—

",

"related third party" means—

(a) an individual with parental responsibility (within the meaning of section 3 of the Children Act 1989(**5**)) for a child to whom personal care services are to be provided;

(b) an individual with power of attorney or other lawful authority to make arrangements on behalf of the person to whom personal care services are to be provided;

(c) a group of individuals mentioned in either of paragraphs (a) and (b) making arrangements on behalf of one or more persons to whom personal care services are to be provided;

(d) a trust established for the purpose of providing services to meet the health or social care needs of a named individual.".

(**5**) 1989 c.41.

(3) In paragraph 6 (assessment or medical treatment for persons detained under the 1983 Act)—

(a) at the beginning of sub-paragraph (1), insert "Subject to sub-paragraph (1A),";

(b) after sub-paragraph (1), insert—

"(1A) Sub-paragraph (1) does not apply to the assessment or treatment by a registered medical practitioner appointed for the purposes of Part 4 of the 1983 Act in giving a certificate under sections 57 (treatment requiring consent and a second opinion), 58 (treatment requiring consent or a second opinion) or 58A (electro-convulsive therapy) of that Act(**6**)."

(4) In paragraph 7 (surgical procedures), after sub-paragraph (1)(a), insert—

"(aa) the purpose of sterilisation or reversal of sterilisation;".

(5) In paragraph 8 (diagnostic and screening procedures)—

(a) in sub-paragraphs (1) and (2), for "sub-paragraph (3)" substitute "sub-paragraphs (3), (4A) and (4C)";

(b) in sub-paragraph (4)—

(i) in paragraph (a)(i), after "pin prick" insert "or from a vein";

(ii) for paragraph (g) substitute—

"(g) the carrying out of a hearing needs assessment or the supply and fitting of a hearing aid carried out by a hearing aid dispenser or a person acting under the direction or supervision of a hearing aid dispenser where —

(i) the patient is aged 19 or over, or

(ii) the patient is under 19 years old and the procedure is carried out in, or arranged by, a school or 16 to 19 Academy;

(h) the taking of urine samples where 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;

(i) the taking and analysing of wound swabs, hair samples or nail clippings;

(j) the non-ambulatory recording of blood pressure;

(k) the use of 12-lead electrocardiography;

(l) the use of a peak flow meter to measure peak expiratory flow;

(m) pulse oximetry when used for the purpose of spot recording;

(n) spirometry when carried out for screening, non-diagnostic or monitoring purposes; and

(o) diagnostic and screening procedures carried out by a person in connection with any of the activities listed in Schedule 2 (activities for which licences may be granted) to the Human Fertilisation and Embryology Act 1990(**7**) for which a licence has been granted to that person under section 16 (grant of licence) of that Act.";

(c) after sub-paragraph (4), insert—

"(4A) Where a service provider is registered in respect of an activity listed in any other paragraph of this Schedule, the procedures specified in sub-paragraph (4B), and

(**6**) 1983 c.20, as amended by Mental Health Act 2007 c.12.
(**7**) 1990 c.37, as amended by section 11 of the Human Fertilisation and Embryology Act 2008 (c.22), S.I. 2007/1522 and S.I. 2009/2232.