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

2009 No. XXXX

NATIONAL HEALTH SERVICE, ENGLAND

The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009

Made - - - -	*2009*
Coming into force - -	*1st April 2009*

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 8(1), 16(a), 20, 30(3), 35, 39(1) and (4), 65(1) and (3), 86(2) and (4), 87, 89 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 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.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009 and shall come into force on 1st April 2009.

(2) These Regulations apply in relation to regulated activity carried on in England.

Interpretation

2. In these Regulations—

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

"patient" includes a woman who is pregnant or breastfeeding, or who has recently given birth;

"treatment" includes nursing, palliative care and a diagnostic or other investigative procedure.

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

Prescribed activities

3.—(1) For the purposes of section 8(1) of the Act, the following activities are prescribed as regulated activities—

(a) the provision of health care to patients by a National Health Service trust or an NHS foundation trust;

(b) the provision of ambulance services, for transporting patients for the purposes of treatment, by a National Health Service trust or an NHS foundation trust;

(c) the provision of health care to patients by a Primary Care Trust; and

(d) the management by NHS Blood and Transplant(**2**) of—

(i) the supply of blood, blood components and blood derived products intended for transfusion;

(ii) the supply of tissues and tissue derived products intended for transplant, grafting or use in a surgical procedure; and

(iii) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.

(2) In this regulation, provision of health care means only services provided directly to patients by the body in question and not those commissioned by that body from a third party.

Register of regulated activities

4. The Commission must establish and maintain a register containing such information as appears to the Commission to be necessary to keep the public informed about the identity of persons registered as service providers and their carrying on of regulated activities.

Regulation of regulated activities

5.—(1) A person registered as a service provider in respect of the carrying on of a regulated activity must, so far as reasonably practicable, ensure that the—

(a) patients;

(b) persons (whether employed or not) working for the purpose of the carrying on of the regulated activity; and

(c) others who may be at risk of exposure to a health care associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

(2) The means referred to in paragraph (1) are—

(a) the effective operation of systems designed to assess the risk of and to prevent, detect, treat and control the spread of, a health care associated infection; and

(b) the maintenance of appropriate standards of design, cleanliness and hygiene in relation to—

(i) premises occupied for the purpose of the carrying on of the regulated activity; and

(ii) equipment used in those premises.

(3) For the purpose of this regulation, "premises" includes a vehicle owned or used by the person registered as a service provider for transporting—

(**2**) NHS Blood and Transplant was established as a Special Health Authority in October 2005 – see S.I. 2005/2529.

(a) patients for the purposes of treatment; and

(b) materials to be used in the treatment of patients in circumstances where such materials are at risk of being contaminated with a health care associated infection.

Offence

6.—(1) A person registered as a service provider who contravenes, or fails to comply with, the provisions of regulation 5 is guilty of an offence.

(2) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine not exceeding £50,000.

Penalty notices

7.—(1) The offences under the provisions listed in the first column of Schedule 1 are prescribed as fixed penalty offences for the purposes of section 86 of the Act.

(2) The monetary amount of the penalty for each fixed penalty offence is prescribed in the second column of Schedule 1.

(3) The time by which the penalty specified in a penalty notice is to be paid is the end of the period of 28 days beginning with the date of receipt of the notice.

(4) The method by which penalties may be paid is by electronic transfer of funds to the Commission's bank account.

(5) Where a person is given a penalty notice, proceedings for the offence to which the notice relates may not be instituted before the end of the period of 28 days beginning with the date of receipt of the notice.

(6) Where a penalty notice is given by being sent by an electronic communication, in accordance with section 94 of the Act, the notice is, unless the contrary is proved, to be taken to have been received on the next working day after the day on which it is sent(**3**).

(7) A penalty notice must give such particulars of the circumstances alleged to constitute the offence as seem to the Commission to be reasonably required to provide the person to whom the notice is given with information about it.

(8) A penalty notice must state—

(a) the name and address of the person to whom the notice is given;

(b) the amount of the penalty;

(c) the period during which proceedings will not be taken for the offence;

(d) that payment within that period will discharge any liability for the offence;

(e) the consequences of the penalty not being paid before the expiration of the period for paying it;

(f) the person to whom and the address at which the penalty may be paid and to which any correspondence about the penalty may be sent; and

(g) the means by which payment of the penalty may be made.

(9) A penalty notice may be withdrawn if—

(a) the Commission determines that it ought not to have been given or it ought not to have been given to the person to whom it was addressed; or

(b) it appears to the Commission that the notice contains material errors.

(**3**) See: section 93(2) of the Act for notices sent by post.

(10) A penalty notice may be withdrawn in accordance with paragraph (9) whether or not the period for payment referred to in paragraph (3) has expired, and whether or not the penalty has been paid.

(11) Where a penalty notice has been withdrawn in accordance with paragraph (9) the Commission must—

(a) give notice of the withdrawal to the person to whom the notice was given;

(b) repay any amount paid by way of penalty in pursuance of that notice to the person who paid it; and

(c) remove from publication information about payment of the penalty which has been published in accordance with paragraph 4 of Schedule 2 prior to withdrawal of the notice to which the payment relates.

(12) Except as provided in paragraph (13), no proceedings may be instituted or continued against the person to whom a penalty notice was given for the offence to which the penalty notice relates where that notice has been withdrawn in accordance with paragraph (9).

(13) Where a penalty notice has been withdrawn pursuant to paragraph (9)(b), proceedings may be instituted or continued for the offence in connection with which that penalty notice was issued if a further penalty notice in respect of the offence has been given and the penalty has not been paid before the expiration of the period for payment referred to in paragraph (3).

(14) In this regulation—

"electronic communication" has the same meaning as in the Electronic Communications Act 2000(**4**); and

"working day" means any day other than—

(a) a Saturday or Sunday;

(b) Christmas Day or Good Friday; or

(c) a day which is a bank holiday in England and Wales under the Banking and Financial Dealings Act 1971(**5**).

Publication of information relating to enforcement action

8.—(1) Except in the circumstances specified in paragraphs 5 to 7 of Part 1 of Schedule 2, the Commission must publish the information prescribed in that Part of that Schedule in the time prescribed in paragraph 8 of that Part.

(2) The Commission may publish the information prescribed in Part 2 of Schedule 2 subject, in the case of the information prescribed in paragraph 11(1), to the condition specified in sub-paragraph (2) of that paragraph.

Exemptions from the requirement to notify bodies of certain matters

9. Section 39(1) of the Act does not apply in the following cases—

(a) a notice given under—

(i) section 26(3) of the Act (notice of proposals); or

(ii) section 28(1) or (3) of the Act (notice of decisions),

to a person who applies for registration as a service provider;

(**4**) 2000 c.7.
(**5**) 1971 c. 80.

(b) a notice of proposal given under section 26(4)(c) or (d) of the Act, or a notice of decision given under section 28(3) of the Act, which—

(i) relates to the variation or removal of any condition for the time being in force in relation to a registration or the imposition of an additional condition in relation to a registration, and

(ii) appears to the Commission not to have a material impact on the regulated activity being carried on;

(c) a notice of proposal given under section 26(5) of the Act or a notice of decision given under section 28(3) of the Act to refuse an application by the service provider under section 19(1)(a), (b) or (c) of the Act; and

(d) a warning notice given under section 29 of the Act which appears to the Commission not to have a material impact on the regulated activity being carried on.

Notification to Primary Care Trust, English local authority and Strategic Health Authority

10.—(1) The Primary Care Trust or English local authority that is required to be given—

(a) notice of an application for an order for cancellation of the registration of a service provider under section 30 of the Act; or

(b) a copy of a notice under section 39 of the Act,

is to be determined in accordance with paragraphs (2) to (5).

(2) Where the application under section 30 of the Act, or the notice of which a copy is required to be given under section 39 of the Act, is in respect of a regulated activity that involves, or is connected with, the provision of health care the Commission must give notice or a copy of the notice to the relevant Primary Care Trust.

(3) Where the application under section 30 of the Act, or the notice of which a copy is required to be given under section 39 of the Act, is in respect of a regulated activity that involves, or is connected with, the provision of social care the Commission must give notice or a copy of the notice to the relevant local authority.

(4) The relevant Primary Care Trust is any Primary Care Trust in whose area the regulated activity is being carried on.

(5) The relevant local authority is any local authority in whose area the regulated activity is being carried on.

(6) The Strategic Health Authority that must be given notice under section 30(3)(b) of the Act or a copy of a notice under section 39(1)(b) of the Act in respect of a regulated activity is any Strategic Health Authority in whose area the regulated activity is being carried on.

Power to require an explanation

11.—(1) Where the Commission considers an explanation of a relevant matter(**6**) necessary or expedient for the purposes of any of its regulatory functions, the persons specified in paragraph (3) must, if so requested, provide an explanation of that matter to the Commission or to persons authorised by it.

(2) Explanations required under paragraph (1) must be provided at such times and such places as may be specified by the Commission.

(3) The persons referred to in paragraph (1) are—

(a) a person carrying on a regulated activity;

(**6**) "Relevant matter" is defined in section 65(2) of the Act.