

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.

- (b) a chair, director or employee of an English NHS body;
- (c) a member of an English NHS body other than an NHS foundation trust;
- (d) a member of a committee or sub-committee of an English NHS body other than an NHS foundation trust;
- (e) a member of a committee or sub-committee of the board of directors of an NHS foundation trust;
- (f) a person (other than a person prescribed in sub-paragraphs (b) to (e)) who is assisting a person carrying on a regulated activity in the provision of that activity;
- (g) a person providing equipment or premises to a person carrying on a regulated activity;
- (h) a chair, director or employee of a person providing equipment or premises to a person carrying on a regulated activity; and
- (i) a person (other than a person prescribed in sub-paragraph (h)) who is assisting a person providing equipment or premises to a person carrying on a regulated activity.

Signed by authority of the Secretary of State for Health.

Date

Name
Minister of State,
Department of Health

SCHEDULE 1

Regulation 7

FIXED PENALTY OFFENCES

<i>Provision creating offence</i>	<i>General nature of offence</i>	<i>Monetary amount of penalty</i>
Regulation 6 of these Regulations	Contravention of, or failure to comply with, requirements relating to a health care associated infection.	£4,000
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
Section 34(1) of the Act	Carrying on a regulated activity whilst registration is suspended.	£4,000
Section 63(7) of the Act	Obstructing entry and inspection.	£1,250
Section 64(4) of the Act	Failure to provide documents and information.	£1,250
Section 65(4) of the Act	Failure to provide an explanation.	£1,250

SCHEDULE 2

Regulation 8

PUBLICATION OF INFORMATION RELATING TO ENFORCEMENT ACTION

PART 1

INFORMATION RELATING TO ENFORCEMENT
ACTION WHICH MUST BE PUBLISHED

1. In relation to the cancellation or suspension of a person's registration under section 17, 18, 30 or 31 of the Act, the prescribed information, subject to paragraph 5, is—

- (a) the name of the person registered as a service provider whose registration has been cancelled or suspended;
- (b) a description of the regulated activity to which the cancellation or suspension relates;
- (c) an explanation of why the registration has been cancelled or suspended and, where applicable, the period of suspension; and
- (d) the address at which the person registered as a service provider is carrying on the regulated activity or, in the case of the provision of ambulance services for the purposes

of transporting patients, such address for the National Health Service trust or the NHS foundation trust providing that service as the Commission considers relevant.

2. In relation to the conviction of any person in respect of an offence under Part 1 of the Act, except an offence under section 76 (disclosure of confidential person information: offence), the prescribed information, subject to paragraph 6, is—

- (a) a description of the offence;
- (b) a description of the regulated activity that the person so convicted is carrying on, or involved in carrying on;
- (c) the name of the person registered as a service provider in respect of that regulated activity; and
- (d) the address at which the person registered as a service provider is carrying on the regulated activity or, in the case of the provision of ambulance services for the purposes of transporting patients, such address for the National Health Service trust or the NHS foundation trust providing that service as the Commission considers relevant.

3.—(1) This paragraph applies to a decision under section 12(5) of the Act to vary or remove a condition for the time being in force in relation to a person's registration, or to impose an additional condition, which—

- (a) takes effect from the time when the notice is given in accordance with section 31 of the Act; or
- (b) appears to the Commission to have a material impact on the regulated activity being carried on.

(2) The prescribed information, subject to paragraph 5, in cases to which this paragraph applies is—

- (a) the name of the person registered as a service provider;
- (b) a description of the regulated activity that the variation or removal of a condition, or the imposition of an additional condition, relates to;
- (c) a description of the condition being varied, removed or imposed and, where applicable, the variation or removal;
- (d) an explanation of why the decision was taken; and
- (e) the address at which the person registered as a service provider is carrying on the regulated activity or, in the case of the provision of ambulance services for the purposes of transporting patients, such address for the National Health Service trust or the NHS foundation trust providing that service as the Commission considers relevant.

4. In relation to the payment by any person of a penalty in accordance with a penalty notice issued under section 86 of the Act and the offence to which the notice relates, the prescribed information is—

- (a) a description of the fixed penalty offence;
- (b) a description of the regulated activity that the person given the penalty notice was carrying on or involved in carrying on;
- (c) the name of the person registered as a service provider in respect of that regulated activity; and
- (d) the address at which the person registered as a service provider is carrying on the regulated activity or, in the case of the provision of ambulance services for the purposes of transporting patients, such address for the National Health Service trust or the NHS foundation trust providing that service as the Commission considers relevant.

5. Where an appeal is brought under section 32 of the Act and the First-tier Tribunal has directed that the Commission's decision is not, or is to cease, to have effect, or the order made by a justice of peace is to cease to have effect, paragraphs 1 and 3 do not apply and the information prescribed must not be published.

6. Where an appeal is brought against a conviction for an offence under Part 1 of the Act and the conviction is quashed, paragraph 2 does not apply and the information prescribed must not be published.

7. Where a penalty notice is withdrawn in accordance with regulation 7(9) after the penalty has been paid but before publication of the information referred to in paragraph 4, that paragraph does not apply and the information must not be published.

8.—(1) The time prescribed for information required to be published under paragraphs 1 and 3 where no appeal is brought under section 32 of the Act is within the period starting immediately after the end of the period of 28 days referred to in section 32(2) of the Act and ending four months after service on the person of the notice of the Commission's decision or the date of the order under section 30 of the Act.

(2) The time prescribed for information required to be published under paragraphs 1 and 3 where an appeal is brought under section 32 of the Act is within 3 months of the determination or abandonment of the appeal.

(3) The time prescribed for information required to be published under paragraph 2 where no appeal is brought against a conviction is within the period starting immediately after the end of the period of 28 days after the date of the conviction and ending four months after date of the conviction.

(4) The time prescribed for information required to be published under paragraph 2 where an appeal is brought against a conviction is within 3 months of the determination or abandonment of the appeal.

(5) The time prescribed for information to be published under paragraph 4 is within three months of the date of payment of the penalty.

PART 2

INFORMATION RELATING TO ENFORCEMENT ACTION WHICH MAY BE PUBLISHED

9. In relation to a conviction in respect of an offence under Part 1 of the Act, except an offence under section 76, the prescribed information is the penalty imposed.

10. Where a person who is not registered as a service provider is convicted of an offence under Part 1 of the Act, except an offence under section 76, the prescribed information is the name of, and such other details as the Commission considers relevant about, the individual convicted of the offence.

11.—(1) In relation to a warning notice given under section 29 of the Act, the prescribed information is—

- (a) the name of the person registered as a service provider who has been given the warning notice;
- (b) a description of the regulated activity to which the warning notice relates;
- (c) a description of the conduct which appears to the Commission to constitute a failure to comply with the relevant requirements and a description of the requirements concerned; and

(d) the address at which the person registered as a service provider is carrying on the regulated activity or, in the case of the provision of ambulance services for the purposes of transporting patients, such address for the National Health Service trust or the NHS foundation trust providing that service as the Commission considers relevant.

(2) The Commission must, before publishing the information prescribed under sub-paragraph (1), provide the person to whom the notice was given an opportunity to make representations to the Commission relating to the matters dealt with in the notice.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which are to come into force on 1st April 2009, are made under the Health and Social Care Act 2008 (“the Act”) and apply in relation to regulated activities carried on in England (regulation 1). Part 1 of the Act establishes the Care Quality Commission (“the Commission”) and provides for the registration of persons carrying on a regulated activity. It also provides powers to make regulations imposing requirements in relation to those regulated activities, and in relation to the Commission’s enforcement powers in respect of persons registered as service providers.

Regulation 2 is an interpretation provision.

Regulation 3 prescribes the activities that are to be regulated activities for the purposes of section 8 of the Act. These are the direct provision of health care to patients by National Health Service trusts, NHS foundation trusts and by Primary Care Trusts, the provision of ambulance services to transport patients by National Health Service trusts or NHS foundation trusts and the activities of NHS Blood and Transplant in relation to transfusion and transplant procedures.

Regulation 4 requires the Commission to keep a register of persons registered as service providers carrying on a regulated activity.

Regulation 5 sets out the requirements that will apply in relation to regulated activities pursuant to section 20 of the Act. For the purposes of protecting patients, health care workers and others who may be at risk of acquiring a health care associated infection, a service provider must effectively operate systems to (a) assess the risks to such persons of acquiring such an infection and (b) prevent, detect, treat and control the spread of such an infection.

In addition, and for the same purposes, a service provider must maintain appropriate standards of design, cleanliness and hygiene in relation to premises and equipment used for carrying on the regulated activities. “Premises” includes vehicles used for transporting patients for the purposes of treatment and materials that are to be used to treat patients in circumstances where such materials are at risk of being contaminated with a health care associated infection.

Regulation 6 provides that a breach of regulation 5 will be an offence punishable, on summary conviction, by a fine of up to £50,000.

Regulation 7 and Schedule 1 prescribe fixed penalty offences for the purposes of section 86 of the Act and the amount of the penalty, and make provision about the time by which a penalty notice must be paid and the method by which payment may be made, the period during which proceedings cannot be instituted for the offence to which the penalty notice relates, the content of the penalty notice and when a penalty notice can be withdrawn.

Regulation 8 and Schedule 2 prescribe information relating to enforcement action that the Commission must publish and the time by which it must be published, and information that the Commission may publish.

Regulation 9 prescribes cases in which copies of notices of proposals given under section 26 of the Act, notices of decisions given under section 28 of the Act and warning notices given under section 29 of the Act do not need to be given to persons listed in section 39 of the Act.

Regulation 10 defines which Primary Care Trust, local authority and Strategic Health Authority is required to be notified by the Commission of an application for an order for cancellation of the registration of a service provider under section 30 of the Act or given a copy of a notice referred to in section 39(2) of the Act.

Regulation 11 requires the persons prescribed to provide an explanation of a relevant matter to the Commission, or to persons authorised by it, in circumstances where the Commission considers the explanation necessary or expedient for the purposes of its regulatory functions. It also gives the Commission power to require the explanation to be given at such times and such places as it specifies.

An impact assessment of the effect that this instrument (together with the Health and Social Care Act 2008 (Commencement No 6, Transitory and Transitional Provisions) Order 2008) ([S.I. 2008/3168](#)) will have on the costs and benefits to the NHS bodies in question, together with an Equality Screening Assessment is available on the Department of Health website at <http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm> and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.