

“non-departmental public body” means a body established by an Act of Parliament, an Act of the Scottish Parliament or by a statutory instrument made under any such Act to perform functions conferred on it under or by virtue of that Act or instrument or any other Act or instrument.

Application

2.—(1) Subject to paragraph (2), these Regulations apply in relation to England, Scotland and Wales.

(2) Part 3 (additional responsibilities of responsible officers) applies in relation to England only.

PART 2

Responsible Officers

Designated bodies

3.—(1) The designation of bodies for the purposes of section 45A of the Act is determined in accordance with the following provisions of this regulation.

(2) The following bodies are designated bodies—

- (a) Primary Care Trusts;
- (b) Local Health Boards;
- (c) National Health Service trusts;
- (d) NHS foundation trusts;
- (e) the Department of Health;
- (f) the Scottish Ministers;
- (g) the Welsh Ministers;
- (h) Strategic Health Authorities;
- (i) Health Boards;
- (j) the faculty of occupational medicine;
- (k) the faculty of public health;
- (l) the faculty of pharmaceutical medicine;
- (m) the Independent Doctors’ Federation;

(3) The following bodies, to the extent that they do not fall within paragraph (2), are designated bodies only if and for so long as they employ or contract with one or more licensed medical practitioners.

- (a) English independent hospitals;
- (b) independent health care services with the meaning of section 2(5) of the Regulation of Care (Scotland) Act 2001(a);
- (c) Special Health Boards;
- (d) the Common Services Agency;
- (e) Special Health Authorities;
- (f) a government department or any executive agency of a government department;
- (g) a non-departmental public body;
- (h) the professional and regulatory bodies listed in the Schedule to these Regulations;

(a) 2001 asp 8; section 2(5) was amended by the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13).

- (i) any organisation which carries out surgical procedures (including all pre-operative and post-operative care associated with such procedures) for—
 - (i) the purpose of treating disease, injuries or disorders;
 - (ii) subject to paragraph (4), cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body; or
 - (iii) the purpose of religious observance.;
- (j) subject to paragraph (5), any organisation which carries out diagnostic and screening procedures involving—
 - (i) the use of X-rays and other methods in order to examine the body through the use of radiation, ultrasound or magnetic resonance imaging;
 - (ii) the use of instruments and equipment which are inserted into the body to—
 - (aa) view its internal parts, or
 - (bb) gather physiological data; and
 - (iii) the use of equipment in order to measure and monitor complex physiological characteristics in major organ systems of the body and to examine bodily tissues, fluids and cells for the purposes of obtaining information on—
 - (aa) the causes and extent of disease, or
 - (bb) the response to a therapeutic intervention.
- (k) any organisation which is engaged in the analysis and reporting of the results of the procedures referred to in sub-paragraph (j);
- (l) any organisation which engages in the management 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;
- (m) any organisation engaged in the termination of pregnancies;
- (n) any organisation engaged in the provision of medical services in slimming clinics, including the prescribing of medicines for the purposes of weight reduction;
- (o) a body engaged in the provision of residential accommodation, together with nursing care;
- (p) a body engaged in the practice of alternative and complementary medicine;
- (q) a body engaged in the provision of first aid treatment and established for that purpose;
- (r) a body engaged in the provision of treatment in a sports ground or gymnasium where it is provided for the sole benefit of persons taking part in sporting activities and events;
- (s) a body engaged in the carrying out of any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990^(a);
- (t) a body engaged in the provision of residential accommodation for a person, together with treatment for drug or alcohol misuse, where acceptance by the person of such treatment is a condition of the provision of the accommodation;
- (u) a body engaged in the provision of medical advice in cases where immediate action or attention is needed or triage provided over the telephone or by electronic mail and established for that purpose, and for the purposes of this provision “triage” means the

(a) 1990 c. 37. Paragraph 1 of Schedule 2 was amended by the Human Fertilisation and Embryology Act 2008 (c. 22), section 11(2), Schedule 2, paragraphs 1 and 2 and section 66, Schedule 8, Part 1 and by S.I. 2007/1522.

assignment of degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment of service users;

- (v) an organisation engaged in the provision of medical services in a surgery or consulting room (which is not part of a hospital) in which such services are provided only under arrangements made on behalf of service users by an insurance provider with whom the service users hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity;

(4) The following cosmetic procedures are excepted from paragraph (3)(i)(ii)—

- (a) ear and body piercing;
- (b) tattooing; and
- (c) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.

(5) The taking and analysis of blood samples is excepted from paragraph (3)(j) where—

- (a) the procedure is carried out by means of a pin prick; or
- (b) it is not necessary to send such samples to a specialist facility for analysis.

Duty to nominate or appoint responsible officers

4.—(1) Subject to paragraph (3), every designated body must nominate or appoint a responsible officer under section 45A of the Act.

(2) When a responsible officer nominated or appointed in accordance with paragraph (1) ceases to hold that position, the designated body must nominate or appoint a replacement as soon as reasonably practicable.

(3) A body which is a designated body in accordance with regulation 3(3) is not required to nominate or appoint a responsible officer if and for so long as there is no prescribed connection under regulation 10 between that body and any medical practitioner.

Duty to nominate or appoint additional responsible officers in cases of conflict of interest

5.—(1) Where—

- (a) a designated body has nominated or appointed a responsible officer in accordance with regulation 4, and
- (b) there is a conflict of interest between that responsible officer and a medical practitioner in respect of whom that officer has responsibilities under regulation 9,

the designated body must nominate or appoint a second responsible officer.

(2) In considering whom to nominate or appoint as a second responsible officer in accordance with paragraph (1), the designated body should ensure that there is no conflict of interest between that person and the medical practitioner referred to in paragraph (1)(b).

(3) Where a second responsible officer has been nominated or appointed in accordance with paragraph (1)—

- (a) that responsible officer shall have responsibilities under regulation 9 in relation to the medical practitioner referred to in paragraph (1)(b), and
- (b) the first responsible officer shall have no responsibilities under that regulation in relation to that medical practitioner.

Conditions for nomination or appointment of responsible officers

6. The following conditions must be satisfied in order for a person to be nominated or appointed as, and to remain as, a responsible officer of a designated body—

- (a) the person must be a licensed medical practitioner;

- (b) the person must, at the time of appointment—
 - (i) have been a registered medical practitioner throughout the previous 5 years; and
 - (ii) practise as a medical practitioner or have done so within the previous 5 years.

Nomination or appointment of one person as responsible officer for two or more designated bodies

7. A single person may be nominated or appointed as the responsible officer for two or more designated bodies where each designated body concerned is satisfied that—

- (a) the person satisfies the conditions in regulation 6;
- (b) the person has the capacity to carry out their responsibilities under regulation 9 for each body, and
- (c) no conflict of interest is likely to arise.

Nomination of responsible officer by the Secretary of State

8.—(1) Subject to paragraphs (2) and (3), the Secretary of State may nominate a responsible officer for a designated body where—

- (a) the designated body has failed to nominate or appoint a responsible officer in accordance with regulation 4; or
- (b) the designated body has nominated or appointed as a responsible officer a person who does not meet the conditions in regulation 6 (conditions for nomination or appointment of responsible officers)

(2) Before making a nomination under paragraph (1) for a designated body in Scotland, the Secretary of State must consult the Scottish Ministers.

(3) Before making a nomination under paragraph (1) for a designated body in Wales, the Secretary of State must consult the Welsh Ministers.

Responsibilities of responsible officers

9.—(1) The responsible officer for a designated body has responsibilities relating to the evaluation of the fitness to practise of every medical practitioner who, in accordance with regulation 10 or 11, has a prescribed connection with that body.

(2) The responsibilities of a responsible officer under paragraph (1) are—

- (a) to ensure that the designated body carries out regular appraisals on medical practitioners in accordance with paragraph (3);
- (b) to establish and implement procedures to address concerns about a medical practitioner's fitness to practise, including the investigation of such concerns and the taking of appropriate follow-up action;
- (c) where appropriate, to refer concerns about the practitioner to the General Council;
- (d) where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Council, to take all reasonably practicable steps to ensure that those conditions or undertakings are complied with;
- (e) to make recommendations to the General Council about medical practitioners' fitness to practice;
- (f) to maintain records of practitioners' fitness to practise evaluations, including appraisals and any other investigations or assessments.

(3) The responsible officer must ensure that appraisals carried out under paragraph (2)(a)—

- (a) obtain information on the extent to which the practitioner meets fitness to practise requirements, and

- (b) take into account all available evidence of the medical practitioner's fitness to practise in the work carried out by the practitioner for the designated body and for any other body during the appraisal period.

(4) Responsible officers must co-operate with the General Council and any of its committees, or any persons authorised by the General Council, in connection with the exercise by them of any of their functions under Part 3A or 5 of the Act.

Connection between designated bodies and medical practitioners

10.—(1) For the purposes of section 45B of the Act, and subject to the following provisions of this regulation and to regulation 11, a designated body has a prescribed connection with a medical practitioner in the following circumstances—

- (a) the medical practitioner is on the designated body's medical performers' list prepared in accordance with—
 - (i) regulation 3(1)(a) of the National Health Service (Performers Lists) Regulations 2004(a),
 - (ii) regulation 3(1)(a) of the National Health Service (Performers Lists) (Wales) Regulations 2004(b), or
 - (iii) regulation 4(1) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004(c);
- (b) where sub-paragraph (a) does not apply, the medical practitioner is employed by the designated body;
- (c) where the medical practitioner is contracted to a locum agency and is working in that capacity in Scotland, the designated body is the Health Board in whose area the practitioner carries out most of their clinical practice;
- (d) the designated body is an independent hospital and the medical practitioner provides services to patients at that hospital;
- (e) where none of sub-paragraphs (a) to (d) applies, the designated body is a body referred to in regulation 3(2)(j) to (l) of these regulations and the medical practitioner is a member of that body;
- (f) where none of the preceding sub-paragraphs applies, the designated body is the Independent Doctors' Federation and the practitioner is a member of that body.

(2) Where a medical practitioner would otherwise have a prescribed connection with more than one designated body under paragraph (1), the prescribed connection is determined as follows—

- (a) subject to sub-paragraph (b), in any case where sub-paragraph (1)(a) (medical practitioner on a performers' list) applies, the prescribed connection is in accordance with that sub-paragraph;
- (b) where a prescribed connection with more than one designated body arises under sub-paragraph (1)(a)—
 - (i) the medical practitioner has a prescribed connection with the designated body for whom the practitioner carries out most of their clinical practice, and
 - (ii) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body, the medical practitioner has a prescribed connection with the designated body which is located the shortest distance from the practitioner's address as registered with the General Council;

(a) S.I. 2004/585; relevant amending instrument is S.I. 2008/1187.
(b) S.I. 2004/1020; relevant amending instrument is S.I. 2006/945.
(c) S.S.I. 2004/114.

- (c) subject to sub-paragraph (d), in any case where sub-paragraph (1)(b) (medical practitioner employed by a designated body) applies, the prescribed connection is in accordance with that sub-paragraph;
- (d) where a prescribed connection with more than one designated body arises under sub-paragraph (1)(b) —
 - (i) the medical practitioner has a prescribed connection with the designated body for whom the practitioner carries out most of their clinical practice, and
 - (ii) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body—
 - (aa) if one and only one of the designated bodies concerned is an NHS body, the medical practitioner has a prescribed connection with that body, and
 - (bb) in any other case, the medical practitioner has a prescribed connection with the designated body which is located the shortest distance from the practitioner’s address as registered with the General Council.
- (e) in any other case—
 - (i) the medical practitioner has a prescribed connection with the designated body for whom the practitioner carries out most of their clinical practice, and
 - (ii) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body—
 - (aa) if one and only one of the designated bodies concerned is an NHS body, the medical practitioner has a prescribed connection with that body, and
 - (bb) in any other case, the medical practitioner has a prescribed connection with the designated body which is located the shortest distance from the practitioner’s address as registered with the General Council.

(3) For the purposes of this regulation, “medical practitioner” means a licensed medical practitioner.

Connection between designated bodies and medical practitioners who are responsible officers

11.—(1) Where a medical practitioner is the responsible officer for a designated body (body A) in accordance with these regulations, the prescribed connection between that practitioner and a designated body for the purposes of section 45B of the Act is determined in accordance with the following provisions of this regulation.

(2) The medical practitioner has a prescribed connection with a designated body (body B) in the following circumstances—

- (a) where body A is in England and is not a Strategic Health Authority, body B is the Strategic Health Authority in whose area body A is located;
- (b) where body A is a Strategic Health Authority, body B is the Department of Health;
- (c) where body A is in Scotland, body B is the Scottish Ministers;
- (d) where body A is in Wales, body B is the Welsh Ministers.

Provision of resources to responsible officers

12.—(1) Subject to paragraph (2), each designated body must provide the responsible officer appointed or nominated for that body with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under Regulation 9.

(2) Where the designated body does not employ its responsible officer, the body must provide the resources referred to in paragraph (1) to—

- (a) where the responsible officer is employed, the employer of the officer, and
- (b) in any other case, the responsible officer.

(3) Where a medical practitioner has a prescribed connection with a designated body by virtue of sub-paragraph (c), (d), (e) or (f) of regulation 10(1), the medical practitioner must provide the designated body with sufficient funds and other resources necessary to enable the responsible officer appointed or nominated for that body to discharge their responsibilities under regulation 9 relating to that medical practitioner.

Duty to have regard to guidance

13. In discharging their responsibilities under regulation 9, responsible officers shall have regard to the following—

- (a) any guidance given by the Secretary of State in accordance with section 45C(2) of the Act;
- (b) any relevant guidance given by the General Medical Council, including Good Medical Practice and guidance on fitness to practise procedures.

Offences

14.—(1) A designated body is guilty of an offence if—

- (a) it fails to comply with regulation 4 (duty to nominate or appoint responsible officers);
- (b) it fails to comply with regulation 12 (provision of resources to responsible officers);
- (c) it prevents a responsible officer from discharging their responsibilities under regulation 9.

(2) An offence under this regulation is punishable on summary conviction by a fine not exceeding level 5 on the standard scale.

PART 3

Additional Responsibilities of Responsible Officers: England

Interpretation of Part 3

15. In this Part—

“the 2008 Act” means the Health and Social Care Act 2008;

Additional responsibilities of responsible officers in England

16.—(1) In addition to the responsibilities in regulation 9, responsible officers for designated bodies in England have the following responsibilities.

(2) In relation to the entry by the designated body into contracts of employment or for the provision of services with medical practitioners, the responsible officer must—

- (a) ensure that medical practitioners have qualifications appropriate to the work to be performed;
- (b) ensure that appropriate references are obtained and checked;
- (c) take any steps necessary to verify the identity of medical practitioners;
- (d) where the designated body is a Primary Care Trust, manage admission to the performers’ list in accordance with the National Health Service (Performers Lists) Regulations 2004; and
- (e) maintain accurate records of all steps taken in accordance with this paragraph.

(3) In relation to monitoring medical practitioners’ conduct and performance, the responsible officer must—

- (a) review regularly the general performance information held by the designated body, including clinical indicators relating to patient outcomes;
 - (b) identify any issues arising from this information relating to medical practitioners, such as variations in individual performance; and
 - (c) ensure that the designated body takes steps to address any such issues.
- (4) In relation to ensuring that appropriate action is taken in response to concerns about medical practitioners' conduct or performance, the responsible officer must—
- (a) initiate investigations with appropriately qualified investigators;
 - (b) ensure that procedures are in place to address concerns raised by patients or staff of the designated body or arising from any other source;
 - (c) ensure that any investigation into the conduct or performance of a medical practitioner takes into account any other relevant matters within the designated body, for example wider concerns about operational or systems issues;
 - (d) ensure that a medical practitioner who is subject to procedures under this regulation, and any person who has raised concerns about a medical practitioner, are kept informed about the progress of the investigation;
 - (e) consider the need for further monitoring of the practitioner's conduct and performance and ensure that this takes place where appropriate;
 - (f) where appropriate—
 - (i) take any steps necessary to protect patients, including removing the medical practitioner from contact with patients, staff or the public;
 - (ii) recommend to the medical practitioner's employer that the practitioner should be suspended or have conditions or restrictions placed on their practice; and
 - (g) identify concerns and ensure that appropriate measures are taken to address these, including but not limited to—
 - (i) requiring the medical practitioner to undergo training or retraining;
 - (ii) offering rehabilitation services;
 - (iii) providing opportunities to increase the medical practitioner's work experience;
 - (iv) addressing any systemic issues within the designated body which may have contributed to the concerns identified;
 - (h) maintain accurate records of all steps taken in accordance with this paragraph.

Duty to have regard to guidance

17. In discharging their responsibilities under regulation 16, responsible officers shall have regard to the following—

- (a) any guidance given by the Secretary of State in accordance with section 120(6) of the 2008 Act; and
- (b) guidance given by the National Clinical Assessment Service division of the National Patient Safety Agency.

Provision of resources to responsible officers

18.—(1) Each designated body must provide its responsible officer with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under Regulation 16.

(2) Where the designated body does not employ its responsible officer, the body must provide the resources referred to in paragraph (1) to—

- (a) where the responsible officer is employed, the employer of the officer, and

(b) in any other case, the responsible officer.

(3) Where a medical practitioner has a prescribed connection with a designated body by virtue of sub-paragraph (c), (d), (e) or (f) of regulation 10(1), the medical practitioner must provide the designated body with sufficient funds and other resources necessary to enable the responsible officer appointed or nominated for that body to discharge their responsibilities under regulation 16 relating to that medical practitioner.

Offences

19.—(1) A designated body is guilty of an offence if—

- (a) it fails to comply with regulation 18 (provision of resources to responsible officers);
- (b) it prevents a responsible officer from discharging their responsibilities under regulation 16.

(2) An offence under this regulation is punishable on summary conviction by a fine not exceeding level 5 on the standard scale.

Signed by authority of the Secretary of State for Health

Address
Date

Name
Parliamentary Under Secretary of State
Department

SCHEDULE

Regulation 3(3)(h)

PROFESSIONAL AND REGULATORY BODIES

1. The College of Emergency Medicine
2. The Royal College of Anaesthetists
3. The Royal College of General Practitioners
4. The Royal College of Obstetricians and Gynaecologists
5. The Royal College of Ophthalmologists
6. The Royal College of Paediatrics and Child Health
7. The Royal College of Pathologists
8. The Royal College of Physicians of Edinburgh
9. The Royal College of Physicians of London
10. The Royal College of Physicians and Surgeons of Glasgow
11. The Royal College of Psychiatrists
12. The Royal College of Radiologists
13. The Royal College of Surgeons of Edinburgh
14. The Royal College of Surgeons of England
15. The General Council
16. The Office of the Health Professions Adjudicator

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations establish arrangements for the introduction of “responsible officers” (“ROs”) under the Medical Act 1983 (“the Act”). ROs will be appointed by health care organisations and will have responsibilities relating to the evaluation of the fitness to practice of doctors who work in the organisation. The regulations come into force on [] 2010.

Part 1 of the regulations contains general provisions: regulation 1 contains citation, commencement date and interpretation provisions and regulation 2 deals with the application of the regulations.

Part 2 of the regulations applies to England, Scotland and Wales. This Part deals with the appointment of ROs under the Act.

Regulation 3 lists the bodies which are “designated bodies” under the Act. These are the bodies that will be required to appoint ROs. Regulation 3(2) lists bodies that are always required to have ROs, for example NHS hospitals; regulation 3(3) lists bodies that will be required to have ROs only while they employ or contract with doctors, for example private clinics.

Regulation 4 sets out the duty on designated bodies to appoint ROs. A body is not required to appoint an RO if all the doctors who work for that body already have a connection under the regulations to another designated body (see regulation 10).

Regulation 5 requires designated bodies to appoint an additional RO in cases where there is a conflict of interest between a doctor and the original RO.

Regulation 6 sets out the conditions that must be met for a person to be appointed as an RO: the person must be a licensed doctor, they must have been a registered doctor for the preceding 5 years, and have practised as such at some point in the last 5 years prior to appointment.

Regulation 7 sets out the conditions that must be satisfied for a person to be appointed as an RO for more than one designated body: the person must be capable of carrying out the ROs’ responsibilities for each body concerned, and there must be no conflict of interest.

Regulation 8 provides that the Secretary of State may appoint an RO to a designated body when the body has failed to do so, or has appointed someone unsuitable. The Secretary of State must consult the Scottish or Welsh Ministers, as applicable, before making such an appointment in Scotland or Wales.

Regulation 9 sets out the responsibilities of ROs. ROs are required to evaluate doctors’ fitness to practise. This includes ensuring that regular appraisals are carried out, developing procedures to address any concerns about doctors’ fitness to practise, and reporting concerns to the General Medical Council where appropriate.

Regulation 10 sets out the “prescribed connection” between designated bodies and doctors. When a doctor is linked to a designated body under this regulation, the RO for that body has responsibilities in respect of the doctor under regulation 9. Where a doctor is on the performers’ list of a primary care organisation, that organisation (usually a Primary Care Trust in England; in Scotland the Health Board) will be the designated body for the doctor. Where the doctor is an employee of a designated body (and is not on a performers’ list), the employing organisation will be the designated body for that doctor. Locums working in Scotland are linked to the Health Board where they carry out most of their work. Where a doctor is providing services to patients in an independent hospital, the independent hospital will be the designated body for that doctor. Where none of the other provisions applies, the doctor will be linked to the professional body of which they are a member. The regulation also sets out an order of priority in the event that the doctor could be connected to more than one body.

Regulation 11 sets out the prescribed connection between designated bodies and doctors who are themselves ROs. It is necessary to have special provisions in these cases because ROs cannot be responsible for evaluating themselves.

Regulation 12 contains a requirement for designated bodies and medical practitioners to provide resources to ROs, regulation 13 contains a duty for ROs to have regard to guidance, and regulation 14 provides that a designated body is guilty of an offence if it fails to comply with the regulations.

Part 3 of the regulations applies to England only. This Part contains additional responsibilities for ROs under section 120 of the Health and Social Care Act 2008.

Regulation 15 deals with the interpretation of Part 3. Regulation 16 sets out the additional responsibilities for ROs in England, which include carrying out pre-employment checks on doctors, monitoring doctors' conduct and performance, and investigating and taking appropriate action to deal with concerns about doctors.

Regulation 17 contains a duty for ROs to have regard to guidance, regulation 18 concerns the requirement for designated bodies and medical practitioners to provide resources to ROs, and regulation 19 provides that a designated body is guilty of an offence if it fails to comply with the regulations.

An impact assessment has been prepared in relation to these Regulations and is available from the Department of Health, Quarry House, Quarry Hill, Leeds LS2 7UE.