

*Draft Regulations laid before Parliament under section 45E(4) of the Medical Act 1983 and section 162(3)(e) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2010 No. 000**

**HEALTH CARE AND  
ASSOCIATED PROFESSIONS**

DOCTORS

The Medical Profession (Responsible  
Officers) Regulations 2010

*Made* - - - - - 000

*Coming into force* - - - 1st January 2011

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 45A of the Medical Act 1983(1) and section 120 of the Health and Social Care Act 2008(2).

The Secretary of State has consulted the Scottish Ministers and the Welsh Ministers in accordance with section 45E(2) of the Medical Act 1983.

A draft of this instrument has been laid before and approved by a resolution of each House of Parliament in accordance with section 45E(4) of that Act and section 162(3)(e) of the Health and Social Care Act 2008.

**PART 1**

General

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Medical Profession (Responsible Officers) Regulations 2010 and shall come into force on 1st January 2011.

(2) In these Regulations—

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- (1) 1983 c. 54; sections 45A to 45F were inserted by section 119 of the Health and Social Care Act 2008 (c. 14). Under section 45F, “appropriate authority” means the Secretary of State in relation to England and Wales or Scotland; section 45F also includes a definition of “prescribed”.
- (2) 2008 c. 14.

“the Act” means the Medical Act 1983;

“armed forces bodies” means the bodies referred to in paragraphs 12 to 14 of the Schedule to these Regulations;

“hospital” has the same meaning as in section 275 of the National Health Service Act 2006<sup>(3)</sup>;

“medical practitioner”, except in regulation 7(1)(b), means a registered medical practitioner<sup>(4)</sup>;

“NHS body” means any of the bodies listed in paragraphs 1 to 6 and 15 to 17 of the Schedule to these Regulations;

“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;

“practising privileges” means the grant, by a person managing a hospital, to a medical practitioner of permission to practise as a medical practitioner in that hospital;

“Scottish training governance body” means a body which exercises, on behalf of Scottish Ministers, functions conferred on Scottish Ministers that relate to education and training relating to the health service, including without prejudice to that generality, functions specified in section 47 of the National Health Service (Scotland) Act 1978<sup>(5)</sup>.

### **Application of these Regulations to armed forces bodies**

2.—(1) These Regulations apply to serving members of the armed forces bodies as if they were employed by those bodies.

(2) For the purposes of paragraph (1) a member of a reserve force is to be treated as a serving member of the armed forces body which that reserve force supports, and for this purpose “reserve force” is to be construed in accordance with section 374 of the Armed Forces Act 2006<sup>(6)</sup>.

(3) Where the sole or main role of a medical practitioner employed by the Ministry of Defence is to work in support of any of the armed forces bodies, for the purposes of these Regulations that medical practitioner shall be treated as employed by that body.

### **Application and extent**

3.—(1) These Regulations, except Part 3, extend to England and Wales, and Scotland.

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

## **PART 2**

### **Responsible Officers**

#### **Designated bodies**

4.—(1) The designation of bodies for the purposes of section 45A of the Act is prescribed as follows.

(2) The bodies listed in Part 1 of the Schedule to these Regulations are designated bodies.

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(3) 2006 c.41.

(4) The definition of “registered medical practitioner” in Schedule 1 to the Interpretation Act 1978 (c.30) was substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.

(5) 1978 c. 29. NHS Education for Scotland is currently the sole body in this class.

(6) 2006 c. 52.

(3) The bodies listed in Part 2 of the Schedule to these Regulations, to the extent that they do not fall within Part 1 of the Schedule, are designated bodies only if and for so long as they employ or contract with one or more medical practitioners.

#### **Duty to nominate or appoint responsible officers**

5.—(1) Subject to the following provisions of this regulation, every designated body must nominate or appoint a responsible officer.

(2) The Department of Health shall nominate or appoint two responsible officers.

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

(4) A body listed in Part 2 of the Schedule to these Regulations which is a designated body by virtue of regulation 4(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 or appearance of bias**

6.—(1) A designated body must nominate or appoint a second responsible officer where—

- (a) the designated body has nominated or appointed a responsible officer in accordance with regulation 5; and
- (b) there is a conflict of interest or an appearance of bias between that responsible officer and a medical practitioner in respect of whom that responsible officer has responsibilities under regulation 11 or 13 (“the relevant practitioner”).

(2) In considering whom to nominate or appoint as a second responsible officer in accordance with paragraph (1), the designated body must ensure that there is no conflict of interest or appearance of bias between the person to be nominated or appointed and the relevant practitioner.

(3) Where a second responsible officer has been nominated or appointed in accordance with paragraph (1), that responsible officer, and not the first responsible officer, has the responsibilities specified in regulation 11 or 13 in relation to the relevant practitioner.

#### **Conditions for nomination or appointment of responsible officers and for remaining as responsible officers**

7.—(1) The following conditions must be satisfied in order for a person to be nominated or appointed as a responsible officer of a designated body under regulation 5 or 6—

- (a) the person must be a medical practitioner; and
- (b) the person must, at the time of appointment, have been a medical practitioner throughout the previous 5 years, and for this purpose “medical practitioner” means a person who was fully registered under the Act.

(2) A responsible officer must continue to be a medical practitioner in order to remain as a responsible officer.

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

8. The same 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 7;
- (b) the person has the capacity to carry out their responsibilities under regulation 11 or 13 for each body; and
- (c) no conflict of interest is likely to arise.

### **Nomination of responsible officer by the Secretary of State**

**9.**—(1) Subject to the following provisions of this regulation, 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 5 or 6; or
- (b) the designated body has nominated or appointed as a responsible officer a person who does not meet the conditions in regulation 7.

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

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

(4) Before making a nomination under paragraph (1) for an NHS Foundation Trust, the Secretary of State must consult the Independent Regulator of NHS Foundation Trusts(7).

### **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 12, a designated body has a prescribed connection with a medical practitioner in the following circumstances—

- (a) the designated body is—
  - (i) a postgraduate medical deanery and the medical practitioner is a doctor in training who is a member of a foundation or specialty training programme managed by that deanery; or
  - (ii) a Scottish training governance body, and the medical practitioner is a doctor in training on a postgraduate medical programme which is managed by that Scottish training governance body and has been approved by the General Council;
- (b) where sub-paragraph (a) does not apply, 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(8);
  - (ii) regulation 3(1)(a) of the National Health Service (Performers Lists) (Wales) Regulations 2004(9); or
  - (iii) regulation 4(1) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004(10);
- (c) where neither sub-paragraph (a) nor (b) applies, the medical practitioner is employed by the designated body;

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(7) The Independent Regulator was established by section 2 of the Health and Social Care (Community Health and Standards) Act 2003 (c. 43) and is continued by section 31 of the National Health Service Act 2006 (c. 41).

(8) S.I. 2004/585; relevant amending instrument is S.I. 2008/1187.

(9) S.I. 2004/1020; relevant amending instrument is S.I. 2006/945.

(10) S.S.I. 2004/114.

- (d) the designated body is a locum agency referred to in paragraph 20 of the Schedule to these Regulations, and the medical practitioner contracts with that agency;
  - (e) sub-paragraph (d) does not apply and—
    - (i) the designated body is a primary care organisation, and for this purpose “primary care organisation” means a body referred to in paragraph 1, 2 or 6 of the Schedule to these Regulations;
    - (ii) the medical practitioner contracts with a locum agency which is not a designated body referred to in paragraph 20 of the Schedule to these Regulations; and
    - (iii) the medical practitioner’s address as registered with the General Council is located within the primary care organisation’s area;
  - (f) the designated body owns or manages a hospital and the medical practitioner has practising privileges in respect of that hospital;
  - (g) where none of the preceding sub-paragraphs applies, the designated body is—
    - (i) the Faculty of Occupational Medicine;
    - (ii) the Faculty of Public Health; or
    - (iii) the Faculty of Pharmaceutical Medicine,and the medical practitioner is a member of that body;
  - (h) 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 as follows—
- (a) in any case where sub-paragraph (a) of paragraph (1) (doctor in training) applies, the prescribed connection is in accordance with that sub-paragraph;
  - (b) subject to sub-paragraph (c) and paragraph (4), in any case where sub-paragraph (b) of paragraph (1) (medical practitioner on a performers list) applies, the prescribed connection is in accordance with that sub-paragraph (b);
  - (c) where a prescribed connection with more than one designated body arises under 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, 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;
  - (d) subject to sub-paragraph (e), in any case where sub-paragraph (c) of paragraph (1) (medical practitioner employed by a designated body) applies, the prescribed connection is in accordance with that sub-paragraph (c);
  - (e) where a prescribed connection with more than one designated body arises under paragraph (1)(c)—
    - (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;
  - (f) where a prescribed connection with more than one designated body arises under paragraph (1)(d) (medical practitioner contracting with a locum agency), the medical practitioner has a prescribed connection with the designated body in respect of which the practitioner carried out most of their clinical practice in the previous calendar year;
  - (g) 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) Where—
- (a) a medical practitioner ("M") would otherwise have a prescribed connection with a designated body;
  - (b) M has a prescribed connection with a designated body under regulations made under section 45A of the Act in relation to Northern Ireland; and
  - (c) M carries out most of M's clinical practice in Northern Ireland,
- M does not have a prescribed connection with a designated body under this regulation.
- (4) Where a medical practitioner is on a designated body's medical performers list in accordance with paragraph (1)(b) and is also employed by an armed forces body—
- (a) the medical practitioner has a prescribed connection with the designated body for whom the practitioner carries out most of their clinical practice; and
  - (b) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body, the prescribed connection is with the armed forces body.
- (5) For the purposes of paragraphs (2)(c)(ii), (2)(e)(ii)(bb) and (2)(g)(ii)(bb), the location of a designated body is the address of its principal office.

### **Responsibilities of responsible officers: prescribed connection under regulation 10**

**11.**—(1) Subject to paragraph (6), the responsible officer for a designated body has the following responsibilities relating to the evaluation of the fitness to practise of every medical practitioner who has a prescribed connection with that body by virtue of regulation 10.

- (2) The responsibilities referred to in 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 investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the designated body or arising from any other source;
  - (c) where appropriate, to refer concerns about the medical practitioner to the General Council;

- (d) where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Council, to monitor compliance with those conditions or undertakings;
- (e) to make recommendations to the General Council about medical practitioners' fitness to practise;
- (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) involve obtaining and taking account of all available information relating to 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) Procedures under paragraph (2)(b) must include provision for the medical practitioner's comments to be sought and taken into account where appropriate.

(5) 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.

(6) Where a responsible officer is nominated or appointed in accordance with regulation 5(2) (Department of Health: two responsible officers), the division of responsibilities under paragraph (1) for each responsible officer is to be determined by the Department of Health.

### **Connection between designated bodies and medical practitioners who are responsible officers**

**12.**—(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 as follows.

(2) Subject to paragraph (3), 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.

(3) A medical practitioner who is a responsible officer for—

- (a) the Department of Health;
- (b) the Scottish Ministers; or
- (c) the Welsh Ministers,

does not have a prescribed connection with a designated body under these Regulations.

### **Responsibilities of responsible officers: prescribed connection under regulation 12**

**13.**—(1) Subject to paragraph (6), the responsible officer for a designated body has the following responsibilities relating to the evaluation of the fitness to practise of every medical practitioner who has a prescribed connection with that body by virtue of regulation 12.

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

- (a) to take all reasonably practicable steps to ensure that the medical practitioner undergoes regular appraisals in accordance with paragraph (3);

- (b) to take all reasonably practicable steps to investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the body for whom the medical practitioner is the responsible officer, or arising from any other source;
  - (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 monitor compliance with those conditions or undertakings;
  - (e) to make recommendations to the General Council about the medical practitioner's fitness to practise;
  - (f) to maintain records of the medical practitioner's fitness to practise evaluations, including appraisals and any other investigations or assessments.
- (3) The responsible officer must take reasonably practicable steps to ensure that appraisals under paragraph (2)(a)—
- (a) are carried out by the body for whom the medical practitioner is the responsible officer; and
  - (b) involve obtaining and taking account of all available information relating to the medical practitioner's fitness to practise in the work carried out by the practitioner during the appraisal period.
- (4) Procedures under paragraph (2)(b) must include provision for the medical practitioner's comments to be sought and taken into account where appropriate.
- (5) 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.
- (6) Where a responsible officer is nominated or appointed in accordance with regulation 5(2) (Department of Health: two responsible officers), the division of responsibilities under paragraph (1) for each responsible officer is to be determined by the Department of Health.

### **Provision of resources to responsible officers**

- 14.—(1) Subject to paragraph (2), each designated body must provide the responsible officer nominated or appointed for that body with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under regulations 11 and 13.
- (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 (d), (e), (f), (g) or (h) of regulation 10(1), the medical practitioner must provide the designated body with sufficient funds necessary to enable the responsible officer nominated or appointed for that body to discharge their responsibilities under regulation 11 relating to that medical practitioner.
- (4) The designated body must determine the amount of the sufficient funds referred to in paragraph (3) and provide to the medical practitioner a written demand for the sum required to be paid.

### **Duty to have regard to guidance**

15. In discharging their responsibilities under regulations 11 and 13, responsible officers shall have regard to the following—
- (a) guidance given by the Secretary of State in accordance with section 45C(2) of the Act; and



- (b) guidance given by the General Council, including Good Medical Practice and guidance on fitness to practise procedures, to the extent that it relates to the nomination or appointment of responsible officers or their prescribed responsibilities.

## PART 3

### Additional Responsibilities of Responsible Officers: England

#### **Additional responsibilities of responsible officers: prescribed connection under regulation 10**

**16.**—(1) Where a responsible officer has responsibilities under regulation 11 in respect of a medical practitioner who has a prescribed connection with a designated body in accordance with regulation 10, the responsible officer has the following additional responsibilities to the extent that the medical practitioner concerned is practising in England.

(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 and experience 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 sub-paragraphs (a) to (d).

(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 outcomes for patients;
- (b) identify any issues arising from that 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;
- (d) consider the need for further monitoring of the practitioner's conduct and performance and ensure that this takes place where appropriate;
- (e) ensure that a medical practitioner who is subject to procedures under this paragraph is kept informed about the progress of the investigation;
- (f) ensure that procedures under this paragraph include provision for the medical practitioner's comments to be sought and taken into account where appropriate;
- (g) where appropriate—
  - (i) take any steps necessary to protect patients;

- (ii) recommend to the medical practitioner’s employer that the practitioner should be suspended or have conditions or restrictions placed on their practice; and
- (h) 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;
- (i) maintain accurate records of all steps taken in accordance with this paragraph.

**Additional responsibilities of responsible officers: prescribed connection under regulation 12**

17.—(1) Where a responsible officer has responsibilities under regulation 13 in respect of a medical practitioner who has a prescribed connection with a designated body in accordance with regulation 12, the responsible officer has the following additional responsibilities to the extent that the medical practitioner concerned is practising in England.

(2) The responsible officer must ensure that the medical practitioner has established systems and procedures which will enable them to carry out their responsibilities under regulation 16(2) effectively.

(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 outcomes for patients;
- (b) identify any issues arising from that information relating to medical practitioners, such as variations in individual performance; and
- (c) take all reasonably practicable steps to ensure that the designated body addresses 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 take all reasonably practicable steps to—

- (a) ensure that the body for whom the medical practitioner is the responsible officer initiates investigations with appropriately qualified investigators;
- (b) ensure that procedures are in place to address concerns raised about the medical practitioner by patients or staff of that 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 that body;
- (d) consider the need for further monitoring of the practitioner’s conduct and performance and take steps to ensure that this takes place where appropriate;
- (e) ensure that a medical practitioner who is subject to procedures under this paragraph is kept informed about the progress of the investigation;
- (f) ensure that procedures under this paragraph include provision for the medical practitioner’s comments to be sought and taken into account where appropriate;
- (g) where appropriate—
  - (i) take any steps necessary to protect patients;

- (ii) recommend to the medical practitioner's employer that the practitioner should be suspended or have conditions or restrictions placed on their practice; and
- (h) 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;
- (i) maintain accurate records of all steps taken in accordance with this paragraph.

### **Duty to have regard to guidance**

**18.** In discharging their responsibilities under regulations 16 and 17, responsible officers must have regard to the following—

- (a) guidance given by the Secretary of State in accordance with section 120(6) of the Health and Social Care Act 2008; and
- (b) guidance given by the National Clinical Assessment Service division of the National Patient Safety Agency<sup>(11)</sup>, to the extent that it relates to the nomination or appointment of responsible officers or their prescribed responsibilities.

### **Provision of resources to responsible officers**

**19.**—(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 regulations 16 and 17.

(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 (d), (e), (f), (g) or (h) of regulation 10(1), the medical practitioner must provide the designated body with sufficient funds necessary to enable the responsible officer nominated or appointed for that body to discharge their responsibilities under regulation 16 relating to that medical practitioner.

(4) The designated body must determine the amount of the sufficient funds referred to in paragraph (3) and provide to the medical practitioner a written demand for the sum required to be paid.

Signed by authority of the Secretary of State for Health

Address  
Date

*Name*  
Parliamentary Under Secretary of State  
Department

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(11) The National Patient Safety Agency is a Special Health Authority established by [S.I. 2001/1743](#).

## SCHEDULE

Regulation 4

### Designated Bodies

Regulation 4(2)

## PART 1

### Designated bodies

1. Primary Care Trusts.
  2. Local Health Boards.
  3. National Health Service trusts.
  4. NHS foundation trusts.
  5. Strategic Health Authorities.
  6. Health Boards.
  7. The Department of Health.
  8. The Scottish Ministers.
  9. The Welsh Ministers.
  10. Postgraduate medical deaneries in England and Wales.
  11. Any Scottish training governance body.
  12. The Royal Navy.
  13. The regular army within the meaning of section 374 of the Armed Forces Act 2006.
  14. The Royal Air Force.
- Regulation 4(3)

## PART 2

### Designated bodies which employ or contract with medical practitioners

15. Special Health Boards.
16. Special Health Authorities.
17. The Common Services Agency for the Scottish Health Service(12).
18. Bodies which provide independent health care services within the meaning of section 2(5) of the Regulation of Care (Scotland) Act 2001(13).
19. A Government department or any executive agency of a Government department.
20. The following locum agencies—

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(12) The Common Services Agency is a non-departmental public body, known as the NHS National Services Scotland. See <http://www.nhsns.org/index.php?id=2>.

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

- (a) limited companies with shares owned wholly by the Secretary of State for Health, which are concerned with the contracting of locum doctors(14); and
  - (b) locum agencies in England and Wales which are participants in the NHS Purchasing and Supply Agency's national framework agreement for the supply of medical locums(15).
21. A non-departmental public body.
22. Any body whose principal office is located in the United Kingdom and whose President or Dean is a member of the Academy of Medical Royal Colleges.
23. Bodies which have functions under the Act in relation to the regulation of medical practitioners(16).
24. The Independent Doctors' Federation.
25. Any organisation engaged in the provision of treatment for disease, disorder or injury by or under the supervision of a medical practitioner.
- 26.—(1) Any organisation which carries out surgical procedures (including any pre-operative and post-operative care associated with such procedures) undertaken by or under the supervision of a medical practitioner who is employed by, or who contracts with, that organisation for—
- (a) the purpose of treating disease, injuries or disorders;
  - (b) subject to sub-paragraph (2), cosmetic purposes, where the procedure involves the use of instruments or equipment which are inserted into the body; or
  - (c) the purpose of religious observance.
- (2) The following cosmetic procedures are excepted from sub-paragraph (1)(b)—
- (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.
- 27.—(1) Subject to sub-paragraph (2), any organisation which carries out diagnostic and screening procedures involving—
- (a) the use of X-rays and other methods in order to examine the body through the use of radiation, ultrasound or magnetic resonance imaging;
  - (b) the use of instruments and equipment which are inserted into the body to—
    - (i) view its internal parts; or
    - (ii) gather physiological data; and
  - (c) 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—
    - (i) the causes and extent of disease; or
    - (ii) the response to a therapeutic intervention.

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(14) Currently the sole member of this class is NHS Professionals Ltd, company number 06704614; see also [www.nhsprofessionals.nhs.uk](http://www.nhsprofessionals.nhs.uk).

(15) Contract reference number CM/AMN/07/4820: period of contract 1 July 2008 to 30 June 2011; responsibility for this agreement transferred from the NHS Purchasing and Supply Agency to Buying Solutions, an executive agency of the Office of Government Commerce, in October 2009. The agreement can be viewed at the following website: <http://www.buyingsolutions.gov.uk/healthcms/Productsandservices/Agencystaffandoutsourcedservices/temporarystaff/Medicallocums/>.

(16) These bodies are the General Medical Council and the Office of the Health Professions Adjudicator.

- (2) The taking and analysis of blood samples is excepted from sub-paragraph (1) 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.
- 28.** Any organisation which is engaged in the analysis and reporting of the results of the procedures referred to in paragraph 27.
- 29.** Any organisation which engages in the management of—
- (a) supply of blood, blood components and blood derived products intended for transfusion;
  - (b) the supply of tissues and tissue-derived products intended for transplant, grafting or use in a surgical procedure; and
  - (c) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.
- 30.** Any organisation engaged in the termination of pregnancies.
- 31.** Any organisation engaged in the provision of medical services in slimming clinics, including the prescribing of medicines for the purposes of weight reduction.
- 32.** A body engaged in the provision of residential accommodation together with nursing care.
- 33.** A body engaged in the provision of first aid treatment and established for that purpose.
- 34.** 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.
- 35.** 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<sup>(17)</sup>.
- 36.** 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.
- 37.** 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 assignment of degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment of patients.
- 38.** An organisation engaged in the provision of medical services (otherwise than in 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.

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(17) 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 I and by S.I. 2007/1522.

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## 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 certain other bodies, and will have responsibilities relating to the evaluation of the fitness to practise of doctors who work in the organisation. The Regulations come into force on 1st January 2011.

Part 1 of the Regulations contains general provisions: regulation 1 contains citation, commencement date and interpretation provisions; regulation 2 contains interpretation provisions for the armed forces, and regulation 3 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 and their responsibilities under the Act.

Regulation 4 and the Schedule specify the bodies which are “designated bodies” under the Act. These are the bodies that will be required to nominate or appoint ROs. Regulation 4(2) and Part 1 of the Schedule list bodies that are always required to have ROs, for example NHS hospitals; regulation 4(3) and Part 2 of the Schedule list bodies that will be required to have ROs only while they employ or contract with doctors, for example, Government departments. Government-owned locum agencies (NHS Professionals Ltd currently being the sole such agency in the class described in paragraph 20(a)) are designated bodies; other locum agencies in England and Wales are designated bodies only if they are on the NHS Purchasing and Supply Agency’s framework agreement (paragraph 20(b) of the Schedule); this agreement can be viewed at the following website:

<http://www.buyingsolutions.gov.uk/healthcms/Productsandservices/Agencystaffandoutsourcedservices/temporarystaff/Medicallocums/>.

Regulation 5 sets out the duty on designated bodies to nominate or appoint ROs. A body is not required to have an RO if all the doctors who work for that body already have a connection under the Regulations with another designated body (see regulation 10).

Regulation 6 requires designated bodies to nominate or appoint an additional RO in cases where there is a conflict of interest or appearance of bias between a doctor and the original RO.

Regulation 7 sets out the conditions that must be met for a person to be nominated or appointed as an RO: the person must be a registered medical practitioner, which under current legislation means a licensed doctor; they must also have been a registered doctor for the preceding 5 years. A responsible officer must continue to be a registered medical practitioner.

Regulation 8 sets out the conditions that must be satisfied for a person to be nominated or 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 9 provides that the Secretary of State may nominate an RO for 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 respect of an NHS body in Scotland or Wales, and must consult the independent regulator (Monitor) before making such an appointment in relation to an NHS Foundation Trust.

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 11. Doctors in training in England and Wales are linked to the postgraduate deanery that is responsible for their training; doctors in training in Scotland are linked

to a Scottish training governance body (NHS Education for Scotland currently being the sole body falling within that class). Where a doctor is on the performers list of a primary care organisation, that organisation (a Primary Care Trust in England, a Health Board in Scotland or a Local Health Board in Wales) will be the designated body for the doctor, except for doctors in the armed forces who will be linked to the organisation where they do most of their work. Where the doctor is an employee of a designated body (and is not a trainee or on a performers list), the employing organisation will be the designated body for that doctor. Doctors working as locums will be linked to their locum agency if that agency is NHS Professionals Ltd, or is on an approved list (the NHS PASA framework) in England and Wales; other locums will be linked to their nearest Primary Care Trust, Health Board or Local Health Board. Where a doctor is providing services to patients in an independent hospital, the body managing that hospital will be the designated body for that doctor. Where none of the other provisions applies and the doctor is a member of one of certain designated professional bodies, the doctor will be linked to that body. A doctor who is a member of the Independent Doctors' Federation ("the IDF") will be linked to that body if none of the preceding provisions applies; the IDF is a body which represents doctors who work outside other structures, and it sought designation under the Regulations during consultations with the Department of Health. 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 responsibilities of ROs in relation to doctors who are connected with the designated body under regulation 10. 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 12 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 13 makes provision similar to regulation 11 in respect of ROs' responsibilities in relation to doctors who are connected with the designated body under regulation 12.

Regulation 14 contains a requirement for designated bodies and medical practitioners to provide resources to ROs, and regulation 15 contains a duty for ROs to have regard to guidance.

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 16 sets out the additional responsibilities for ROs in England in respect of the doctors for whom they are responsible under regulation 10; these 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 makes similar provision for ROs' responsibilities in relation to doctors for whom they are responsible under regulation 12.

Regulation 18 contains a duty for ROs to have regard to guidance, and regulation 19 concerns the requirement for designated bodies and medical practitioners to provide resources to ROs.

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; see also <http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment>.