
DRAFT STATUTORY INSTRUMENTS

2010 No.

**The Medical Profession (Responsible
Officers) Regulations 2010**

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—

“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⁽¹⁾;

“medical practitioner”, except in regulation 7(1)(b), means a registered medical practitioner⁽²⁾;

“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⁽³⁾.

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.

⁽¹⁾ 2006 c.41.

⁽²⁾ 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.

⁽³⁾ 1978 c. 29. NHS Education for Scotland is currently the sole body in this class.

(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⁽⁴⁾.

(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.

(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

(4) 2006 c. 52.

- (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⁽⁵⁾.

(5) 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).

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⁽⁶⁾;
 - (ii) regulation 3(1)(a) of the National Health Service (Performers Lists) (Wales) Regulations 2004⁽⁷⁾; or
 - (iii) regulation 4(1) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004⁽⁸⁾;
- (c) where neither sub-paragraph (a) nor (b) applies, the medical practitioner is employed by the designated body;
- (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—

⁽⁶⁾ S.I. 2004/585; relevant amending instrument is S.I. 2008/1187.

⁽⁷⁾ S.I. 2004/1020; relevant amending instrument is S.I. 2006/945.

⁽⁸⁾ S.S.I. 2004/114.

- (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⁽⁹⁾, 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

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