
DRAFT STATUTORY INSTRUMENTS

2010 No.

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

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
- (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(1).

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—

(1) 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).

- (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(2);
 - (ii) regulation 3(1)(a) of the National Health Service (Performers Lists) (Wales) Regulations 2004(3); or
 - (iii) regulation 4(1) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004(4);
 - (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—
- (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);

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

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

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

- (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.