

2010 No. 222

HEALTH AND PERSONAL SOCIAL SERVICES

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

Laid before the Assembly in draft

Made - - - - 23rd June 2010

Coming into operation - 1st October 2010

The Department of Health, Social Services and Public Safety makes the following Regulations in exercise of the powers conferred by section 45A of the Medical Act 1983(a) and section 120 of the Health and Social Care Act 2008(b).

PART 1

General

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010 and shall come into operation on 1st October 2010.

(2) In these Regulations—

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

“the Act” means the Medical Act 1983;

“clinical practice” includes medical practice or professional practice;

“the Department” means the Department of Health, Social Services and Public Safety;

“Health and Social Care Regulation and Quality Improvement Authority” means the body established under the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003(c);

“a Health and Social Care Trust” means a body established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991(d);

“hospital” has the same meaning as in Article 2(2) of the Health and Personal Social Services (Northern Ireland) Order 1972(e);

(a) 1983 c.54; sections 45A to 45F were inserted by section 119 of the Health and Social Care Act 2008 (c. 14).

(b) 2008 c.14.

(c) S.I.2003/431 (N.I.9) renamed by section 1(2)(a) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 c.1 (N.I.)

(d) S.I.1991/194 (N.I.1)

(e) S.I.1972/1265 (N.I.14)

“HSC body” means any of the bodies listed in section 1(5) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(a);

“medical practitioner” except in regulation 5(1)(b) means a fully registered person within the meaning of the Act who holds a licence to practise under the Act;

“medical services” means services provided by a medical practitioner;

“non-departmental public body” means a body, other than a Northern Ireland department, established by a statutory provision to perform functions conferred on it under that statutory provision or any other statutory provision;

“Northern Ireland Blood Transfusion Service” means the special agency established by Order(b) under Article 3 of the Health and Personal Social Services (Special Agencies)(Northern Ireland)Order 1990(c);

“Northern Ireland Medical and Dental Training Agency” means the special agency established by Order(d) under Article 3 of the Health and Personal Social Services (Special Agencies)(Northern Ireland)Order 1990;

“nursing home” and “residential care home” have the same meanings as in the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003;

“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;

“Primary medical services performers list” means the list prepared in accordance with regulation 4 of the Health and Personal Social Services (Primary Medical Services Performers Lists) Regulations (Northern Ireland) 2004(e);

“the Regional Agency for Public Health and Social Well-Being” means the body established under section 12 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

“the Regional Business Services Organisation” means the body established under section 14 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

“the Regional Health and Social Care Board” means the body established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009.

“a special health and social care agency” means a special agency established under Article 3 of the Health and Social Services (Special Agencies) (Northern Ireland) Order 1990.

(3) The Interpretation Act (Northern Ireland)1954 shall apply to these Regulations as it applies to an Act of the Assembly(f).

PART 2

Responsible Officers

Designated bodies

2.—(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 are designated bodies.

(3) The bodies listed in Part 2 of the Schedule, 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.

(a) 2009 c.1(N.I.)

(b) S.R. 1994 No.175

(c) S.I. 1990/247 (N.I.3)

(d) S.R. 2004 No.62

(e) S.R.2004 No.149 as amended by S.R.2008 No.434

(f) 1954 c.33(N.I.)

Duty to nominate or appoint responsible officers

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

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

(3) A body listed in Part 2 of the Schedule which is a designated body by virtue of regulation 2(3) is not required to nominate or appoint a responsible officer if, and for so long as, there is no prescribed connection under regulation 8 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

4.—(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 3; 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 officer has responsibilities under regulation 9 or 11 (“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 9 or 11 in relation to the relevant practitioner.

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

5.—(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 3 or 4—

- (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 at the relevant time.

(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

6. 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 5;
- (b) the person has the capacity to carry out their responsibilities under regulation 9 or 11 for each body; and
- (c) no conflict of interest is likely to arise.

Nomination of responsible officer by the Department

7. The Department 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 3 or 4; or
- (b) the designated body has nominated or appointed as a responsible officer a person who does not meet the conditions in regulation 5.

Connection between designated bodies and medical practitioners

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

- (a) the designated body is the Northern Ireland Medical and Dental Training Agency and the medical practitioner is a doctor in training managed by the Agency;
- (b) where sub-paragraph (a) is not applicable, the medical practitioner is on the designated body’s primary medical services performers’ list;
- (c) where neither sub-paragraph (a) nor (b) applies, the medical practitioner is employed by the designated body;
- (d) the designated body owns or manages a hospital and the medical practitioner has practising privileges in respect of that hospital;
- (e) where none of the preceding sub-paragraphs applies, the designated body is a body referred to in paragraphs 15 to 17 of the Schedule and the medical practitioner is a member of that body;
- (f) where none of the preceding sub-paragraphs applies, the designated body is the Independent Doctors’ Federation and the medical 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 paragraph (1)(a) (doctor in training) applies, the prescribed connection is in accordance with that paragraph;
- (b) in any case where paragraph (1)(b)(medical practitioner on the primary medical services performers list) applies, the prescribed connection is in accordance with that paragraph;
- (c) subject to sub-paragraph (d), in any case where paragraph (1)(c) (medical practitioner employed by a designated body) applies, the prescribed connection is in accordance with that paragraph;
- (d) 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 medical practitioner carries out most of their clinical practice, and
 - (ii) if there is no significant difference in the amount of clinical practice which the medical practitioner carries out for each designated body—
 - (aa) if one and only one of the designated bodies concerned is an HSC 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 medical practitioner’s address as registered with the General Council;
- (e) in any other case—
 - (i) the medical practitioner has a prescribed connection with the designated body for whom the medical practitioner carries out most of their clinical practice, and
 - (ii) if there is no significant difference in the amount of clinical practice which the medical practitioner carries out for each designated body—
 - (aa) if one and only one of the designated bodies concerned is an HSC 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 medical 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 England, Wales or Scotland ; and
- (c) M carries out most of M's clinical practice in England, Wales or Scotland,

M does not have a prescribed connection with a designated body under this regulation.

(4) For the purposes of paragraph (2)(d)(ii)(bb) and (2)(e)(ii)(bb) the location of a designated body is the address of its principal office.

Responsibilities of responsible officers: prescribed connection under regulation 8

9.—(1) 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 8.

(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 medical 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) obtain and take into account all available information relating to the medical practitioner's fitness to practise in the work carried out by the medical 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.

Connection between designated bodies and medical practitioners who are responsible officers

10.—(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 medical 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 a Health and Social Care Trust, body B is the Regional Agency for Public Health and Social Well-Being;
- (b) where body A is the Regional Health and Social Care Board, body B is the Regional Agency for Public Health and Social Well-Being;
- (c) where body A is the Northern Ireland Blood Transfusion Service, body B is the Regional Agency for Public Health and Social Well-Being;
- (d) where body A is the Regional Agency for Public Health and Social Well-Being, body B is the Department;
- (e) where body A is the Northern Ireland Medical and Dental Training Agency, body B is the Department;
- (f) where body A is the Health and Social Care Regulation and Quality Improvement Authority, body B is the Department;
- (g) where body A is not a body referred to in sub-paragraphs (a) to (f) body B is the Health and Social Care Regulation and Quality Improvement Authority.

(3) The medical practitioner who is the responsible officer for the Department does not have a prescribed connection with a designated body under these Regulations.

Responsibilities of responsible officers: prescribed connection under regulation 10

11.—(1) 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 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 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 the medical practitioners’ fitness to practice;
- (f) to maintain records of the medical practitioners’ 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) obtain and take into account all available information relating to the medical practitioner’s fitness to practise in the work carried out by the medical 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.

Provision of resources to responsible officers

12.—(1) Subject to paragraph (2), each designated body must provide the responsible officer appointed or nominated for that body with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under regulations 9 and 11.

(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) or (f) of regulation 8(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 9 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

13. In discharging their responsibilities under regulations 9 and 11, responsible officers shall have regard to the following—

- (a) guidance given by the Department in accordance with section 45C(2) of the Act;
- (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

Additional responsibilities of responsible officers: prescribed connection under regulation 8

14.—(1) Where a responsible officer has responsibilities under regulation 9 in respect of a medical practitioner who has a prescribed connection with a designated body in accordance with regulation 8, the responsible officer has the following additional responsibilities.

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

- (a) review regularly the general performance information held by the designated body, including clinical indicators relating to patient outcomes;
- (b) identify any issues arising from this information relating to medical practitioners, such as variations in individual performance; and
- (c) ensure that the designated body takes steps to address any such issues.

(3) In relation to ensuring that appropriate action is taken in response to concerns about medical practitioners' conduct or performance, the responsible officer must—

- (a) initiate investigations with appropriately qualified investigators;
- (b) ensure that procedures are in place to address concerns raised by patients or staff of the designated body or arising from any other source;
- (c) ensure that any investigation into the conduct or performance of a medical practitioner takes into account any other relevant matters within the designated body, for example wider concerns about operational or systems issues;

- (d) consider the need for further monitoring of the medical 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 medical 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 10

15.—(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.

(2) 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.

(3) 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 medical 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

16. In discharging their responsibility under regulations 14 and 15, responsible officers shall have regard to the following—

- (a) guidance given by the Department in accordance with section 120(6) of the 2008 Act; and
- (b) guidance given by the National Clinical Assessment Service division of the National Patient Safety Agency(a), to the extent that it relates to the nomination or appointment of responsible officers or their prescribed responsibilities.

Provision of resources to responsible officers

17.—(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 14 and 15.

(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) or (f) of regulation 8(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 14 relating to that medical practitioner.

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

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 23rd June 2010



Diane Taylor
A senior officer of the
Department of Health, Social Services and Public Safety

(a) See S.I.2001/1743

SCHEDULE 1

PART 1

Regulation 2(2)

Designated bodies

1. A Health and Social Care Trust.
2. The Regional Health and Social Care Board.
3. The Regional Agency for Public Health and Social Well-Being.
4. The Department.
5. Northern Ireland Medical and Dental Training Agency.

PART 2

Regulation 2(3)

Designated bodies which employ or contract with medical practitioners

6. A Northern Ireland department.
7. Health and Social Care Regulation and Quality Improvement Authority.
8. Northern Ireland Blood Transfusion Service.
9. Regional Business Services Organisation.
10. A non-departmental public body.
11. Faculties of medicine at universities and colleges of further education.
12. Special Health and Social Care Agencies.
13. Pharmaceutical companies.
14. The Independent Doctors' Federation.
15. The faculty of occupational medicine.
16. The faculty of public health medicine.
17. The faculty of pharmaceutical medicine.
18. Any organisation engaged in the provision of treatment for disease, disorder or injury by or under the supervision of a medical practitioner.
- 19.—(1) Any organisation which carries out surgical procedures (including all pre-operative and post-operative care associated with such procedures) 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.

20.—(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.

(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.

21. Any organisation which is engaged in the analysis and reporting of the results of the procedures referred to in paragraph 20.

22. 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.

23. Any organisation engaged in the provision of medical services in slimming clinics, including the prescribing of medicines for the purposes of weight reduction.

24. A residential care home.

25. A nursing home.

26. A body engaged in the practise of alternative and complementary medicine.

27. A body engaged in the provision of first aid treatment and established for that purpose.

28. 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.

29. A body engaged in the carrying out of any of the activities authorised by a licence granted by the Human Fertilisation and Embryology Authority under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990(a).

30. 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.

31. 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.

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

32. 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.

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

Part 1 of the Regulations contains general provisions: regulation 1 contains citation, commencement date and interpretation provisions.

Part 2 of the Regulations deals with the appointment of ROs and their responsibilities under the Act.

Regulation 2 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 2(2) and Part 1 of the Schedule list bodies that are always required to have ROs, for example Health and Social Care Trusts; regulation 2(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 a Northern Ireland department.

Regulation 3 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 8).

Regulation 4 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 5 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 6 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 7 provides that the Department may nominate an RO for a designated body when the body has failed to do so, or has appointed someone unsuitable.

Regulation 8 sets out the “prescribed connection” between designated bodies and doctors. When a doctor is linked to a designated body under this regulation, the RO for that body has responsibilities in respect of the doctor under regulation 9. Doctors in training are linked to the Northern Ireland Medical and Dental Training Agency which is responsible for their training. Where a doctor is on the performers’ list held by the Regional Health and Social Care Board, that organisation will be the designated body for the doctor. Where the doctor is an employee of a designated body (and is not on the performers’ list), the employing organisation will be the designated body for that doctor. 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, the doctor will be linked to the professional body of which they are a member. The regulation also sets out an order of priority in the event that the doctor could be connected to more than one body.

Regulation 9 sets out the responsibilities of ROs in relation to doctors who are connected with the designated body under regulation 8. 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 Council where appropriate.

Regulation 10 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 11 makes provision similar to regulation 9 in respect of ROs' responsibilities in relation to doctors who are connected with the designated body under regulation 10.

Regulation 12 contains a requirement for designated bodies and medical practitioners to provide resources to ROs, and regulation 13 contains a duty for ROs to have regard to guidance.

Part 3 contains additional responsibilities for ROs under section 120 of the Health and Social Care Act 2008.

Regulation 14 sets out the additional responsibilities for ROs in respect of the doctors for whom they are responsible under regulation 8; these include monitoring doctors' conduct and performance and investigating and taking appropriate action to deal with concerns about doctors.

Regulation 15 makes similar provision for ROs' responsibilities in relation to doctors for whom they are responsible under regulation 10.

Regulation 16 contains a duty for ROs to have regard to guidance, and regulation 17 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, Social Services and Public Safety, Castle Buildings, Stormont, Belfast, BT4 3SQ.

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HEALTH AND PERSONAL SOCIAL SERVICES

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

£5.75