
DRAFT STATUTORY RULES OF NORTHERN
IRELAND

2010 No.

HEALTH AND PERSONAL SOCIAL SERVICES

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

Made - - - -

Coming into operation -

The Department of Health, Social Services and Public Safety makes the following regulations in exercise of the powers conferred by sections 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 [Date to be inserted] 2010.

(2) In these Regulations –

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

“the Act” means the Medical Act 1983;

“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);

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

“independent hospital” has the meaning given in Article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003;

“licensed medical practitioner” means a registered medical practitioner who holds a licence to practise;

“medical services” means services provided by a licensed 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(a) under Article 3 of the Health and Personal Social Services (Special Agencies)(Northern Ireland)Order 1990(b);

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

“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(d);

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

“registered medical practitioner” has the same meaning as in the Interpretation Act 1978(e);

(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 determined in accordance with the following provisions of this regulation.

(2) The following bodies are designated bodies for the purposes of section 45A of the Act—

- (a) a Health and Social Care Trust;
- (b) the Regional Health and Social Care Board;
- (c) the Regional Agency for Public Health and Social Well-Being;
- (d) the Department;
- (e) the Independent Doctors’ Federation;
- (f) independent hospitals;
- (g) the faculty of occupational medicine of the Royal College of Physicians of London(g);
- (h) the faculty of public health medicine of the Royal College of Physicians of London;

(a) S.R. 1994 No.175

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

(c) S.R. 2004 No.62

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

(e) 1978 c.30

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

(g) Incorporated by Royal Charter dated 23 September 1518

- (i) the faculty of pharmaceutical medicine of the Royal College of Physicians of London;
- (j) Health and Social Care Regulation and Quality Improvement Authority;
- (k) Northern Ireland Medical and Dental Training Agency.

(3) The following bodies, to the extent that they do not fall within paragraph (1), are designated bodies only if and for so long as they employ or contract with one or more licensed medical practitioners—

- (a) a Northern Ireland department;
- (b) a non-departmental public body;
- (c) pharmaceutical companies;
- (d) any organisation which carries out surgical procedures (including all pre-operative and post-operative care associated with such procedures) for—
 - (i) the purpose of treating disease, injuries or disorders,
 - (ii) subject to paragraph (4) cosmetic purposes, where the procedure involves the use of instruments and equipment which are inserted into the body, or
 - (iii) the purpose of religious observance;
- (e) subject to paragraph (5), any organisation which carries out diagnostic and screening procedures involving—
 - (i) the use of X-rays and other methods in order to examine the body through the use of radiation, ultrasound or magnetic resonance imaging,
 - (ii) the use of instruments and equipment which are inserted into the body to—
 - (aa) view its internal parts, or
 - (bb) gather physiological data; and
 - (iii) the use of equipment in order to measure and monitor complex physiological characteristics in major organ systems of the body and to examine bodily tissues, fluids and cells for the purposes of obtaining information on—
 - (aa) the causes and extent of disease, or
 - (bb) the response to a therapeutic intervention;
- (f) any organisation which is engaged in the analysis and reporting of the results of the procedures referred to in sub-paragraph (e);
- (g) any organisation which engages in the management of—
 - (i) the supply of blood, blood components and blood derived products intended for transfusion,
 - (ii) the supply of tissues and tissue derived products intended for transplant, grafting or use in a surgical procedure, and
 - (iii) the matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion;
- (h) any organisation engaged in the provision of medical services in slimming clinics, including the prescribing of medicines for the purpose of weight reduction;
- (i) a body engaged in the provision of residential accommodation, together with nursing care;
- (j) a body engaged in the practise of alternative and complementary medicine;
- (k) a body engaged in the provision of first aid treatment and established for that purpose;
- (l) a body engaged in the provision of treatment in a sports grounds or gymnasium where it is provide for the sole benefit of persons taking part in sporting activities and events;

- (m) 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);
 - (n) a body engaged in the provision of residential accommodation for a person, together with treatment for drug or alcohol misuse, where acceptance by a person of such treatment is a condition of the provision of the accommodation;
 - (o) 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 assignment of degrees of urgency to diseases, disorders or injuries in order to decide the order and place of treatment of service users;
 - (p) an organisation engaged in the provision of medical services in a surgery or consulting room (which is not part of a hospital) in which such services are provided only under arrangements made on behalf of service users by an insurance provider with whom the service users hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity.
- (4) The following cosmetic procedures are excepted from paragraph 3(d)(ii)—
- (a) ear and body piercing;
 - (b) tattooing; and
 - (c) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.
- (5) The taking and analysis of blood samples is excepted from paragraph (3)(e) where—
- (a) the procedure is carried out by means of a pin prick; or
 - (b) it is not necessary to send such samples to a specialist facility for analysis.

Duty to nominate or appoint responsible officers

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

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

(3) A body which is a designated body in accordance with regulation 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 9 between that body and any medical practitioner.

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

4.—(1) Where—

- (a) a designated body has nominated or appointed a responsible officer in accordance with regulation 3; and
- (b) there is a conflict of interest between that responsible officer and a medical practitioner in respect of whom that officer has responsibilities under regulation 8;

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

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

(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.

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

- (a) that responsible officer shall have responsibilities under regulation 8 in relation to the medical practitioner referred to in paragraph (1)(b); and
- (b) the first responsible officer shall have no responsibilities under that regulation in relation to that medical practitioner.

Conditions for nomination or appointment of responsible officers

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

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

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

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

- (a) the person satisfies the conditions in regulation 5;
- (b) the person has the capacity to carry out their responsibilities under regulation 8 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 appoint a responsible officer in accordance with regulation 3; or
- (b) the designated body has nominated or appointed as a responsible officer a person who does not meet the conditions in regulation 5 (Conditions for nomination or appointment of responsible officers).

Responsibilities of responsible officers

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

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

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

- (e) to make recommendations to the General Medical Council about medical practitioners' fitness to practice;
 - (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)—
- (a) contain information on the extent to which the medical practitioner meets fitness to practise requirements; and
 - (b) take into account all available evidence of the medical practitioner's fitness to practise in the work carried out by the medical practitioner for the designated body and for any other body during the appraisal period.
- (4) Responsible officers must co-operate with the General Medical Council and any of its committees, or any persons authorised by the General Medical 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

9.—(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 medical practitioner is on the designated body's primary medical services performers' list;
 - (b) where sub-paragraph (a) does not apply, the medical practitioner is employed by the designated body;
 - (c) the designated body is an independent hospital and the medical practitioner provides services to patients at that hospital;
 - (d) where none of sub-paragraphs (a) to (c) applies, the designated body is a body referred to in regulation 2(2)(g) to (j) of these regulations and the medical practitioner is a member of that body;
 - (e) 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 determined as follows—
- (a) in any case where sub-paragraph (1)(a) (medical practitioner on the primary medical services performers list) applies, the prescribed connection is in accordance with that sub-paragraph;
 - (b) subject to sub-paragraph (c), in any case where sub-paragraph (1)(b) (medical practitioner employed by a designated body) applies, the prescribed connection is in accordance with that sub-paragraph;
 - (c) where a prescribed connection with more than one designated body arises under sub-paragraph (1)(b) —
 - (i) the medical practitioner has a prescribed connection with the designated body for whom the 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 Medical Council;
 - (d) 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 Medical Council.

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

Connection between designated bodies and medical practitioners who are responsible officers

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 determined in accordance with the following provisions of this regulation.

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

- (a) where body A is 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.

Provision of resources to responsible officers

11.—(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 8.

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

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

(3) Where a medical practitioner has a prescribed connection with a designated body by virtue of sub-paragraph (c), (d) or (e) of regulation 9(1), the medical practitioner must provide the designated body with sufficient funds and other resources necessary to enable the responsible officer appointed or nominated for that body to discharge their responsibilities under regulation 8 relating to that medical practitioner.

Duty to have regard to guidance

12. In discharging their responsibilities under regulations 8, responsible officers shall have regard to the following—

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

Offences

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

- (a) it fails to comply with regulation 3 (Duty to nominate or appoint responsible officers);
- (b) it fails to comply with regulation 11 (Provision of resources to responsible officers);
- (c) it prevents a responsible officer from discharging their responsibilities under regulations 8.

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

PART 3

Additional Responsibilities of Responsible Officers

Additional responsibilities for responsible officers under the 2008 Act

14.—(1) In addition to the responsibilities in regulation 8, responsible officers for designated bodies have the following 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) ensure that a medical practitioner who is subject to procedures under this regulation, and any person who has raised concerns about a medical practitioner, are kept informed about the progress of the investigation;
- (e) consider the need for further monitoring of the medical practitioner's conduct and performance and ensure that this takes place where appropriate;
- (f) where appropriate—
 - (i) take any steps necessary to protect patients, including removing the medical practitioner from contact with patients, staff or the public;

- (ii) recommend to the medical practitioner's employer that the medical practitioner should be suspended or have conditions or restrictions placed on their practice; and
- (g) identify concerns and ensure that appropriate measures are taken to address these, including but not limited to—
 - (i) requiring the medical practitioner to undergo training or retraining;
 - (ii) offering rehabilitation services;
 - (iii) providing opportunities to increase the medical practitioner's work experience;
 - (iv) addressing any systemic issues within the designated body which may have contributed to the concerns identified;
- (h) maintain accurate records of all steps taken in accordance with this paragraph.

Duty to have regard to guidance

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

- (a) any guidance given by the Department in accordance with section 120(6) of the 2008 Act; and
- (b) guidance given by the National Patient Safety Agency(a)

Provision of resources to responsible officers

16.—(1) Each designated body must provide its responsible officer with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under regulation 14.

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

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

(3) Where a medical practitioner has a prescribed connection with a designated body by virtue of sub-paragraph (c), (d) or (e) of regulation 9(1), the medical practitioner must provide the designated body with sufficient funds and other resources necessary to enable the responsible officer appointed or nominated for that body to discharge their responsibilities under regulation 8 relating to that medical practitioner.

Offences

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

- (a) it fails to comply with regulation 16 (Provision of resources to responsible officers);
- (b) it prevents a responsible officer from discharging their responsibilities under regulations 14.

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

(a) See S.I.2001/1743

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on



Dr. J.F. Livingstone
A senior officer of the
Department of Health, Social Services and Public Safety

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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 will have responsibilities relating to the evaluation of the fitness to practice of doctors who work in the organisation. 2010. The regulations come into force on

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

Regulation 3 sets out the duty on designated bodies to appoint ROs. A body is not required to appoint an RO if all the doctors who work for that body already have a connection under the regulations to another designated body (see regulation 9).

Regulation 4 requires designated bodies to appoint an additional RO in cases where there is a conflict of interest between a doctor and the original RO

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

Regulation 6 sets out the conditions that must be satisfied for a person to be appointed as an RO for more than one designated body: the person must be capable of carrying out the ROs’ responsibilities for each body concerned, and there must be no conflict of interest.

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

Regulation 8 sets out the responsibilities of ROs. ROs are required to evaluate doctors’ fitness to practise. This includes ensuring that regular appraisals are carried out, developing procedures to address any concerns about doctors’ fitness to practise, and reporting concerns to the General Medical Council where appropriate.

Regulation 9 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 8. Where a doctor is on the performers’ list held by the Business Service Organisation, that organisation will be the designated body for the doctor. Where the doctor is an employee of a designated body (and is not on a performers’ list), the employing organisation will be the designated body for that doctor. Where a doctor is providing services to patients in an independent hospital, the independent hospital will be the designated body for that doctor. Where none of the other provisions applies, the doctor will be linked to the professional body of which they are a member. The regulation also sets out an order of priority in the event that the doctor could be connected to more than one body.

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

Regulation 14 sets out the additional responsibilities for ROs under section 120 of the Health and Social Care Act 2008.

Regulation 15 contains a duty for ROs to have regard to guidance, regulation 16 concerns the requirement for designated bodies and medical practitioners to provide resources to ROs and

regulation 17 provides that a designated body is guilty of an offence if it fails to comply with the regulations.

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