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

DRAFT STATUTORY INSTRUMENTS

2010 No. 000

HEALTH CARE AND ASSOCIATED PROFESSIONS

DOCTORS

The Medical Profession (Responsible Officers) Regulations 2010

Made - - - -	*000*
Coming into force - -	*1st January 2011*

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

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

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

PART 1

General

Citation, commencement and interpretation

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

(2) In these Regulations—

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

(**2**) 2008 c. 14.

"the Act" means the Medical Act 1983;

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

"hospital" has the same meaning as in section 275 of the National Health Service Act 2006(**3**);

"medical practitioner", except in regulation 7(1)(b), means a registered medical practitioner(**4**);

"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(**5**).

Application of these Regulations to armed forces bodies

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

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

(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**) 2006 c.41.
(**4**) The definition of "registered medical practitioner" in Schedule 1 to the Interpretation Act 1978 (c.30) was substituted by S.I. 2002/3135, Schedule 1, paragraph 10 with effect from 16th November 2009.
(**5**) 1978 c. 29. NHS Education for Scotland is currently the sole body in this class.
(**6**) 2006 c. 52.

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

Duty to nominate or appoint responsible officers

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

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

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

(4) A body listed in Part 2 of the Schedule to these Regulations which is a designated body by virtue of regulation 4(3) is not required to nominate or appoint a responsible officer if, and for so long as, there is no prescribed connection under regulation 10 between that body and any medical practitioner.

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

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

(a) the designated body has nominated or appointed a responsible officer in accordance with regulation 5; and

(b) there is a conflict of interest or an appearance of bias between that responsible officer and a medical practitioner in respect of whom that responsible officer has responsibilities under regulation 11 or 13 ("the relevant practitioner").

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

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

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

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

(a) the person must be a medical practitioner; and

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

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

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

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

(a) the person satisfies the conditions in regulation 7;

(b) the person has the capacity to carry out their responsibilities under regulation 11 or 13 for each body; and

(c) no conflict of interest is likely to arise.

Nomination of responsible officer by the Secretary of State

9.—(1) Subject to the following provisions of this regulation, the Secretary of State may nominate a responsible officer for a designated body where—

(a) the designated body has failed to nominate or appoint a responsible officer in accordance with regulation 5 or 6; or

(b) the designated body has nominated or appointed as a responsible officer a person who does not meet the conditions in regulation 7.

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

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

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

Connection between designated bodies and medical practitioners

10.—(1) For the purposes of section 45B of the Act, and subject to the following provisions of this regulation and to regulation 12, a designated body has a prescribed connection with a medical practitioner in the following circumstances—

(a) the designated body is—

(i) a postgraduate medical deanery and the medical practitioner is a doctor in training who is a member of a foundation or specialty training programme managed by that deanery; or

(ii) a Scottish training governance body, and the medical practitioner is a doctor in training on a postgraduate medical programme which is managed by that Scottish training governance body and has been approved by the General Council;

(b) where sub-paragraph (a) does not apply, the medical practitioner is on the designated body's medical performers list prepared in accordance with—

(i) regulation 3(1)(a) of the National Health Service (Performers Lists) Regulations 2004(**8**);

(ii) regulation 3(1)(a) of the National Health Service (Performers Lists) (Wales) Regulations 2004(**9**); or

(iii) regulation 4(1) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004(**10**);

(c) where neither sub-paragraph (a) nor (b) applies, the medical practitioner is employed by the designated body;

(**7**) The Independent Regulator was established by section 2 of the Health and Social Care (Community Health and Standards) Act 2003 (c. 43) and is continued by section 31 of the National Health Service Act 2006 (c .41).
(**8**) S.I. 2004/585; relevant amending instrument is S.I. 2008/1187.
(**9**) S.I. 2004/1020; relevant amending instrument is S.I. 2006/945.
(**10**) S.S.I. 2004/114.

(d) the designated body is a locum agency referred to in paragraph 20 of the Schedule to these Regulations, and the medical practitioner contracts with that agency;

(e) sub-paragraph (d) does not apply and—

(i) the designated body is a primary care organisation, and for this purpose "primary care organisation" means a body referred to in paragraph 1, 2 or 6 of the Schedule to these Regulations;

(ii) the medical practitioner contracts with a locum agency which is not a designated body referred to in paragraph 20 of the Schedule to these Regulations; and

(iii) the medical practitioner's address as registered with the General Council is located within the primary care organisation's area;

(f) the designated body owns or manages a hospital and the medical practitioner has practising privileges in respect of that hospital;

(g) where none of the preceding sub-paragraphs applies, the designated body is—

(i) the Faculty of Occupational Medicine;

(ii) the Faculty of Public Health; or

(iii) the Faculty of Pharmaceutical Medicine,

and the medical practitioner is a member of that body;

(h) where none of the preceding sub-paragraphs applies, the designated body is the Independent Doctors' Federation and the practitioner is a member of that body.

(2) Where a medical practitioner would otherwise have a prescribed connection with more than one designated body under paragraph (1), the prescribed connection is as follows—

(a) in any case where sub-paragraph (a) of paragraph (1) (doctor in training) applies, the prescribed connection is in accordance with that sub-paragraph;

(b) subject to sub-paragraph (c) and paragraph (4), in any case where sub-paragraph (b) of paragraph (1) (medical practitioner on a performers list) applies, the prescribed connection is in accordance with that sub-paragraph (b);

(c) where a prescribed connection with more than one designated body arises under paragraph (1)(b)—

(i) the medical practitioner has a prescribed connection with the designated body for whom the practitioner carries out most of their clinical practice; and

(ii) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body, the medical practitioner has a prescribed connection with the designated body which is located the shortest distance from the practitioner's address as registered with the General Council;

(d) subject to sub-paragraph (e), in any case where sub-paragraph (c) of paragraph (1) (medical practitioner employed by a designated body) applies, the prescribed connection is in accordance with that sub-paragraph (c);

(e) where a prescribed connection with more than one designated body arises under paragraph (1)(c)—

(i) the medical practitioner has a prescribed connection with the designated body for whom the practitioner carries out most of their clinical practice; and

(ii) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body—

(aa) if one and only one of the designated bodies concerned is an NHS body, the medical practitioner has a prescribed connection with that body; and