

**2013 No. 391**

**HEALTH CARE AND ASSOCIATED PROFESSIONS**

**DOCTORS**

**The Medical Profession (Responsible Officers) (Amendment)  
Regulations 2013**

*Made* - - - - *18th February 2013*

*Laid before Parliament* *27th February 2013*

*Coming into force* - - *1st April 2013*

The Secretary of State 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).

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

**Citation, commencement and interpretation**

**1.**—(1) These Regulations may be cited as the Medical Profession (Responsible Officers) (Amendment) Regulations 2013 and shall come into force on 1st April 2013.

(2) In these Regulations—

“the 2010 Regulations” means the Medical Profession (Responsible Officers) Regulations 2010(c).

**Amendment to Part 1 (General)**

**2.**—(1) Part 1 of the 2010 Regulations is amended as follows.

(2) In regulation 1(2)—

(a) for the definition “NHS body” substitute—

““NHS body” means any of the bodies listed in paragraphs 1 to 6, 15 to 17 and 25C of the Schedule to these Regulations;”;

(b) in the appropriate places insert—

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(a) 1983 c. 54; sections 45A to 45F (Part V Responsible Officers) were inserted by section 119 of the Health and Social Care Act 2008 (c. 14); ‘prescribed’ means prescribed by Regulations; and the ‘appropriate authority’ means the Secretary of State in relation to England and Wales and Scotland.

(b) 2008 c. 14.

(c) S.I. 2010/2841.

““the Board” means the National Health Service Commissioning Board(a);

“sufficient number of responsible officers” means the number of responsible officers required to ensure that each responsible officer appointed under regulation 5(2) has the capacity to carryout their responsibilities in regulations 11 and 13.”.

### **Amendment to Part 2 (Responsible Officers)**

3.—(1) Part 2 of the 2010 Regulations is amended as follows.

(2) For regulation 5 substitute—

#### **“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 Board must nominate or appoint a sufficient number of responsible officers.

(3) When a responsible officer nominated or appointed in accordance with paragraph (1) or (2) ceases to hold that position, subject to paragraph (4), the designated body must nominate or appoint a replacement as soon as reasonably practicable.

(4) When a responsible officer nominated or appointed in accordance with paragraph (2) ceases to hold that position, the Board is not required to nominate or appoint a replacement if, in its opinion, there remains a sufficient number of responsible officers appointed or nominated under that paragraph.

(5) Subject to paragraph (6), 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.

(6) Paragraph (5) does not apply where a medical practitioner would have, but for the application of regulation 12, a prescribed connection with a designated body under regulation 10.”.

(3) In regulation 9(1)(a) (nomination of responsible officer by the Secretary of State) after “responsible officer” insert “or a sufficient number of responsible officers”.

(4) In regulation 10 (connection between designated bodies and medical practitioners)—

(a) before paragraph (1)(a) insert—

“(za) the designated body is the Faculty of Medical Leadership and Management(b) and the medical practitioner holds the post of either the National Medical Director or National Deputy Medical Director of the Board;”;

(b) after paragraph (1)(a)(i) insert—

“(ia) a Local Education and Training Board(c) and the medical practitioner is a doctor in training who is a member of a foundation or speciality training programme managed by that Board; or”;

(c) in paragraph (1)(b)—

(i) for “where sub-paragraph (a) does not apply” substitute “where none of the preceding sub-paragraphs apply”,

(ii) after “medical performers list” insert “or ophthalmic performers list”;

(d) for paragraph (1)(b)(i) substitute—

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(a) The National Health Service Commissioning Board was established by section 1H of the National Health Service Act 2006 (c. 41) as inserted by section 9 of the Health and Social Care Act 2012 (c. 7).

(b) The Faculty of Medical Leadership and Management was established in 2011 and works to promote excellence in leadership on behalf of all doctors in public health, primary and secondary care, and at all stages of a medical career.

(c) Local Education and Training Boards are committees of Health Education England.

- “(i) regulations 3(1)(a) or 3(1)(c) (as the case may be) of the National Health Service (Performers Lists) (England) Regulations 2013(a);”;
- (e) after paragraph (1)(b)(iii) insert—
- “(ba) where none of the preceding sub-paragraphs apply, the designated body is Public Health England(b) and the medical practitioner is employed by a local authority in England;
- (bb) where none of the preceding sub-paragraphs apply, the designated body is the Pathology Delivery Board and the medical practitioner is on the Home Office Register of Forensic Pathologists(c);”;
- (f) for paragraph (c) substitute—
- “(c) where none of the preceding sub-paragraphs apply, the medical practitioner is employed by the designated body;”;
- (g) for regulation (f) substitute—
- “(f) the designated body owns or manages a hospital and the medical practitioner has responsibility for treating patients in that hospital in accordance with practising privileges for that hospital;”;
- (h) for regulation (g) substitute—
- “(g) where none of the preceding sub-paragraphs apply, the designated body is—
- (i) the Faculty of Occupational Medicine,
- (ii) the Faculty of Public Health,
- (iii) the Faculty of Pharmaceutical Medicine,
- (iv) the Faculty of Homeopathy,
- (v) the Faculty of Medical Leadership and Management, or
- (vi) the British College of Aesthetic Medicine,
- and the medical practitioner is a member of that body, or where the medical practitioner is a member of more than one of those bodies, that body with which the medical practitioner has been a member for the longest period;”.
- (5) In regulation 11 (responsibilities of responsible officers: prescribed connection under regulation 10) for paragraph (6) substitute—
- “(6) Where a responsible officer is nominated or appointed in accordance with regulation 5(2) (the Board: sufficient number of responsible officers) the division of responsibilities under paragraph (1) for each responsible officer is to be determined by the Board.”.
- (6) For regulation 12 (connection between designated bodies and medical practitioners who are responsible officers) substitute—

**“Connection between designated bodies and medical practitioners who are responsible officers**

**12.—**(1) A registered medical practitioner who is a responsible officer for a body referred to in column 1 of the table has, for the purposes of section 45B of the Act, a prescribed connection with the body, Department or persons referred to in the corresponding entry in column 2 of that table.

**Table**

| <i>Column 1</i> | <i>Column 2</i> |
|-----------------|-----------------|
|-----------------|-----------------|

- (a) S.I. 2013/335.
- (b) Public Health England is an executive agency of the Department of Health.
- (c) Admission to the Home Office Register of Forensic Pathologists is controlled by the Pathology Delivery Board and in particular by its sub committee, Registration and Training, which reviews all applications on behalf of that Board.

| <i>(Body of which a registered medical practitioner is a responsible officer)</i>                                                                                                                | <i>(Body with which there is a prescribed connection)</i> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| 1. Any Government department or executive agency of a Government department in England.                                                                                                          | 1. Department of Health.                                  |
| 2. Any non-departmental public body in England except the Board.                                                                                                                                 | 2. Department of Health.                                  |
| 3. Local Education and Training Boards.                                                                                                                                                          | 3. Health Education England(a).                           |
| 4. Any body in England not falling within the preceding entries except—<br>(a) the Board,<br>(b) Faculty of Medical Leadership and Management.                                                   | 4. the Board.                                             |
| 5. The Board in respect of a medical practitioner appointed or nominated under regulation 5(2) who holds the post of National Medical Director or National Deputy Medical Director of the Board. | 5. the Faculty of Medical Leadership and Management.      |
| 6. The Board in respect of a medical practitioner appointed or nominated under regulation 5(2) and not falling in the preceding entry.                                                           | 6. the Board.                                             |
| 7. Any body in Scotland.                                                                                                                                                                         | 7. the Scottish Ministers.                                |
| 8. Any body in Wales.                                                                                                                                                                            | 8. the Welsh Ministers.                                   |

(2) A medical practitioner who is a responsible officer for—

- (a) the Department of Health;
- (b) the Scottish Ministers;
- (c) the Welsh Ministers; or
- (d) the Faculty of Medical Leadership and Management,

does not have a prescribed connection with a designated body under these Regulations.”.

(7) In regulation 13 (responsibilities of responsible officers: prescribed connection under regulation 12) for paragraph (6) substitute—

“(6) Where a responsible officer is nominated or appointed in accordance with regulation 5(2) (the Board: sufficient number of responsible officers) the division of responsibilities under paragraph (1) for each responsible officer is to be determined by the Board.”.

(8) In regulation 14 (provision of resources to responsible officers) in the first line of paragraph (1) after “the responsible officer” insert “or responsible officers (as the case may be)”.

### **Amendments to Part 3 (additional responsibilities of responsible officers: England)**

4.—(1) Part 3 of the 2010 Regulations is amended as follows.

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(a) Health Education England was established as a Special Health Authority on 28th June 2012 by the Health Education England (Establishment and Constitution) Order 2012 (S.I. 2012/1273).

(2) In regulation 16 (additional responsibilities of responsible officers: prescribed connection under regulation 10)—

(a) after paragraph (2)(a) insert—

“(aa) ensure that medical practitioners have sufficient knowledge of the English language necessary for the work to be performed in a safe and competent manner;”  
;

(b) for paragraph 2(d) substitute—

“(d) where the designated body is the Board, manage admission to the medical performers list in accordance with the National Health Service (Performers Lists) Regulations 2013(a);”.

(3) In regulation 18 (duty to have regard to guidance) for paragraph (b) substitute—

“(b) guidance given by the National Clinical Assessment Service division of the National Health Service Litigation Authority(b), to the extent that it relates to the nomination or appointment of responsible officers or their prescribed responsibilities; and

(c) guidance given by the Board to the extent that it relates to the responsible officer’s duties under regulation 16(2)(aa).”.

(4) In regulation 19 (provision of resources to responsible officers) in the first line of paragraph (1) after “its responsible officer” insert “or responsible officers (as the case may be)”.

#### **Amendments to the Schedule (Designated Bodies)**

**5.**—(1) Part 1 of the Schedule (designated bodies) to the 2010 Regulations is amended as follows.

(2) In paragraph 1 for “Primary Care Trusts” substitute “the Board”.

(3) In paragraph 3 for “National Health Service trusts” substitute “National Health Service trusts other than Ambulance Trusts”.

(4) In paragraph 4 for “NHS foundation trusts” substitute “NHS foundation trusts other than Ambulance Trusts”.

(5) Omit paragraph 5 (Strategic Health Authorities).

(6) After paragraph 14 insert—

“**14A.** Local Education and Training Boards.

**14B.** Pathology Delivery Board.”.

**6.**—(1) Part 2 of the Schedule (designated bodies which employ or contract with medical practitioners) to the 2010 Regulations is amended as follows.

(2) For paragraph 20(b) substitute—

“(b) locum agencies in England and Wales which supply medical locums under the Framework Agreement for the supply of locum doctors (including locum general practitioners) to NHS bodies and the wider public sector(c).”.

(3) After paragraph 25 insert—

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- (a) Regulation 2(1) of S.I. 2013/335 defines a “medical performers list” as a list of medical practitioners prepared and maintained by the Board and published pursuant to regulation 1(3)(a) of those Regulations.
- (b) The Secretary of State issued directions (SI 2012/476) to the National Institute for Health and Clinical Excellence (NICE) on 1st April 2012, under sections 7 and 8 of the National Health Service Act 2006 (c. 41) to carry out functions relating to the National Clinical Assessment Service (the NCAS function). NICE is being abolished as a Special Health Authority on 1st April 2013 and the National Health Service Litigation Authority (NHSLA) will be directed by the Secretary of State to carry out the NCAS function from that date; the NHSLA was established as a Special Health Authority by article 2 of the National Health Service Litigation Authority (Establishment and Constitution Order) 1995 (S.I. 1995/2800).
- (c) Contract reference number RM1570: responsibility for this agreement is with the Government Procurement Service, an executive agency of the Cabinet Office.

**“25A.** Any organisation engaged in providing the services of medical practitioners to work as resident medical officers in independent hospitals.

**25B.** Any organisation engaged in providing medical defence services to medical practitioners in respect of claims for medical negligence or professional misconduct.

**25C.** Ambulance Trusts.

**25D.** The British College of Aesthetic Medicine.

**25E.** The Faculty of Homeopathy.”.

Signed by authority of the Secretary of State for Health.

*Earl Howe*  
Parliamentary Under-Secretary of State,  
Department of Health

18th February 2013

### **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations amend the Medical Profession (Responsible Officers) Regulations 2010 (S.I. 2010/2841) (“the 2010 Regulations”).

Regulation 2 makes amendments to the definition of “NHS body” which is consequential on the changes made to designated bodies in the Schedule. Further definitions are also added to the 2010 Regulations.

Regulation 3(2) makes changes to the duty to nominate a responsible officer. The National Health Service Commissioning Board (“the Board”) has a duty to appoint a sufficient number of responsible officers to ensure that each responsible officer so appointed has the capacity to carry out their duties under regulations 11 and 13 of the 2010 Regulations. Where a responsible officer appointed by the Board ceases to hold that position the Board are only required to nominate a replacement officer if they do not consider they have a sufficient number already appointed. All other designated bodies are required to appoint one responsible officer, unless they are bodies designated under Part 2 of the Schedule to the 2010 Regulations, in which case they are only required to appoint a responsible officer if they have a connection under regulation 10 with any medical practitioner. The effect of the amended regulation 5(6) provides that where a medical practitioner would have had a connection with a body under regulation 10 but for the fact that they were appointed as a responsible officer and therefore have a connection under regulation 12, regulation 5(5) will not apply so that the designated body is required to appoint a responsible officer in those circumstances.

Regulation 3(3) is a consequential amendment which enables the Secretary of State to nominate a responsible officer to the Board where the Board have failed to appoint a sufficient number of responsible officers.

Regulation 3(4) makes further connections between designated bodies and medical practitioners. It also amends the connection between private hospitals and medical practitioners with practising privileges so that the connection is only made where the medical practitioner is treating patients in the hospital. It also makes provision where a medical practitioner is a member of more than one body under regulation 10(1)(g) of the 2010 Regulations so that the medical practitioner is connected to the body with which they have been a member for the longest period.

Regulations 3(5) and 3(7) make provision for the Board to determine the division of responsibilities under regulations 11 and 13 respectively of the 2010 Regulations for each responsible officer.

Regulation 3(6) amends regulation 12 of the 2010 Regulations which prescribes the connections between designated bodies and medical practitioners who are responsible officers. A responsible

officer nominated by any non-departmental public body in England, except the Board, or any Government department or executive agency of a Government Department in England, will be connected to the Department of Health; a responsible officer nominated by Local Education and Training Boards will be connected to Health Education England; a responsible officer who holds the post of NHS Medical Director or NHS Deputy Medical Director of the Board will be connected to the Faculty of Medical Leadership and Management; a responsible officer nominated by any other body in England will be connected to the Board; a responsible officer nominated by a body in Scotland will be connected to the Scottish Ministers; and a responsible officer nominated by a body in Wales will be connected to the Welsh Ministers. This regulation also prescribes that the Faculty of Medical Leadership and Management does not have a prescribed connection to a designated body under the 2010 Regulations.

Regulation 4 amends regulation 16 of the 2010 Regulations which imposes additional responsibilities on responsible officers in England. Regulation 4(2) places an additional duty on responsible officers to ensure that medical practitioners for whom they are responsible have sufficient knowledge of the English language necessary for the work to be performed in a safe and competent manner. Regulation 4(2) also makes a consequential amendment to regulation 16(2)(d) so that responsible officers at the Board will be responsible for managing the admission of medical practitioners to the performers list.

Regulation 4(3) amends regulation 18 (guidance) of the 2010 Regulations. A consequential amendment is made to paragraph (b) to reflect the transfer of functions of the National Clinical Assessment Service, from the Institute for Health and Clinical Excellence to the National Health Service Litigation Authority, on the 1<sup>st</sup> April 2013. An additional provision is inserted which requires responsible officers to have regard to guidance given by the Board in relation to responsible officers duties in respect of language knowledge.

Regulation 5 amends Part 1 of the Schedule to the 2010 Regulations. Primary Care Trusts has been substituted with the Board; Strategic Health Authority has been omitted; Ambulance Trusts have been omitted from Part 1 of the Schedule and added to Part 2 of the Schedule with the effect that Ambulance Trusts will only be required to appoint a responsible officer if they employ one or more medical practitioners and have a connection with a medical practitioner under regulation 10; Local Education and Training Boards and the Pathology Delivery Board have been added as designated bodies under Schedule 1.

Regulation 6 amends Part 2 of the Schedule to the Regulations. Organisations which are engaged in providing the services of medical practitioners to work as resident medical officers in independent hospitals, and organisations which provide medical defence services to medical practitioners in respect of claims for medical negligence or professional misconduct, have been prescribed as designated bodies under Part 2. Ambulance Trusts, the British College of Aesthetic Medicine, and the Faculty of Homeopathy have also been prescribed as designated bodies under Part 2. Paragraph 20(b) of the Schedule is amended to substitute the NHS Purchasing and Supply Agency's national framework agreement with the new Framework Agreement for the supply of medical locums.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Department of Health, Skipton House, 80 London Road, London, SE1 6LH and is published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk)



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STATUTORY INSTRUMENTS

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