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.

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.

Notes

\(^1\) 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”.

Extent

Preamble: England, Wales, Scotland

PART 1

General

\(\text{Law In Force}\)

1. — Citation, commencement and interpretation

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

"the 2006 Act" means the National Health Service Act 2006;
"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;
"the Board" means the National Health Service Commissioning Board;
"hospital" has the same meaning as in section 275 of the National Health Service Act 2006;
"integrated care provider" means a person, other than a person specified in regulation 1A(3), who is party to an integrated care provider contract;
"integrated care provider contract" has the meaning given in regulation 1A;
"medical practitioner", except in regulation 7(1)(b), means a registered medical practitioner;
"NHS body" means any of the bodies listed in paragraphs 1 to 6, 15 to 17 and 25C 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;
"primary medical services" has the meaning given in regulation 1A(7);
"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;
"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 carry out their responsibilities in regulations 11 and 13.

Notes

1 Definition inserted by Amendments Relating to the Provision of Integrated Care Regulations 2019/248 Pt 4 reg.14 (April 1, 2019)
2 Definition inserted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.2(2)(b) (April 1, 2013)
3 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).
4 Definitions inserted by Amendments Relating to the Provision of Integrated Care Regulations 2019/248 Pt 4 reg.14 (April 1, 2019)
5 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.
6 Definition substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.2(2)(a) (April 1, 2013)
7 NHS Education for Scotland is currently the sole body in this class.

Commencement

Pt 1 reg. 1(1)-(2) definition of "Scottish training governance body": January 1, 2011
[1A.— \textbf{Integrated care provider contracts}]

(1) For the purposes of these Regulations, an integrated care provider contract is a contract entered into on or after 1st April 2019 which satisfies the following paragraphs.

(2) An integrated care provider contract must be between—
   \begin{enumerate}
   \item one or more of the persons specified in paragraph (3); and
   \item a person who is a provider of services specified in paragraph (5).
   \end{enumerate}

(3) The persons specified in this paragraph are—
   \begin{enumerate}
   \item the Board;
   \item one or more CCGs; or
   \item one or more local authorities in England.
   \end{enumerate}

(4) An integrated care provider contract must—
   \begin{enumerate}
   \item relate to the provision of two or more services specified in paragraph (5); and
   \item not be a contract to which paragraph (6) applies.
   \end{enumerate}

(5) The services specified in this paragraph are—
   \begin{enumerate}
   \item primary medical services;
   \item secondary care services;
   \item public health services; and
   \item adult social care services,
   \end{enumerate}

and include such services where they are provided under arrangements entered into by an NHS body or a local authority in England by virtue of section 75 of the 2006 Act\(^{2}\).

(6) This paragraph applies to a contract for the provision of primary medical services to which directions given by the Secretary of State under section 98A of the 2006 Act (exercise of functions) relating to the provision of alternative provider medical services under section 83(2) of the 2006 Act apply\(^{3}\).

(7) In this regulation—
   \begin{enumerate}
   \item "adult social care services" means services provided pursuant to the exercise of the adult social services functions of a local authority in England;
   \item "adult social services functions" means social services functions within the meaning of section 1A of the Local Authority and Social Services Act 1970 so far as relating to persons aged 18 or over, excluding any function to which Chapter 4 of Part 8 of the Education and Inspections Act 2006 applies;
   \item "CCG" means a clinical commissioning group established by section 14D of the 2006 Act\(^{4}\);
   \item "primary medical services" means services which the Board considers appropriate to secure the provision of under section 83(2) of the 2006 Act (primary medical services)\(^{5}\);
   \item "public health functions" means—
   \begin{enumerate}
   \item the public health functions of the Secretary of State under the following provisions of the 2006 Act—
   \begin{enumerate}
   \item section 2A (Secretary of State's duty as to protection of public health)\(^{6}\);
(ii) section 2B (functions of local authorities and Secretary of State as to improvement of public health)\(^7\);  
(iii) paragraph 8 and 12 of Schedule 1 (further provision about the Secretary of State and services under this Act)\(^8\);  
(b) the public health functions of a local authority in England under the following provisions of the 2006 Act, and any regulations made under these provisions—  
(i) section 2B (functions of local authorities and Secretary of State as to improvement of public health);  
(ii) section 111 (dental public health)\(^9\);  
(iii) paragraphs 1 to 7B or 13 of Schedule 1 (further provision about the Secretary of State and services under this Act)\(^10\);  
(c) the public health functions of the Secretary of State that a local authority in England is required to exercise by virtue of regulations made under section 6C(1) (regulations as to the exercise by local authorities of certain public health functions)\(^11\) of the 2006 Act; or  
(d) the public health functions of the Secretary of State where they are exercised by the Board, a CCG or a local authority in England, where those bodies are acting pursuant to arrangements made under section 7A (exercise of the Secretary of Health's public health functions)\(^12\) of the 2006 Act;  
"public health services" means services which are provided pursuant to the exercise of public health functions;  
"secondary care services" means—  
(a) such services, accommodation or facilities as a CCG considers it appropriate to make arrangements for the provision of under or by virtue of section 3 (duties of clinical commissioning groups as to commissioning of health services)\(^13\) or 3A (power of clinical commissioning groups to commission certain health services)\(^14\) of the 2006 Act; or  
(b) such services or facilities as the Board is required by the Secretary of State to arrange by virtue of regulations made under section 3B (power to require Board to commission certain health services)\(^15\) of the 2006 Act.

(8) For the purposes of this regulation, any of the following is a local authority in England—  
(a) a county council;  
(b) a county borough council;  
(c) a district council;  
(d) a London borough council;  
(e) the Common Council of the City of London;  
(f) the Council of the Isles of Scilly.

\(^1\) Added by Amendments Relating to the Provision of Integrated Care Regulations 2019/248 Pt 4 reg.15 (April 1, 2019)

\(^2\) See regulation 4 of S.I. 2000/617. Regulation 4 was amended by S.I. 2003/629, 2012/3094 and 2015/1940. See also section 275(1) of the 2006 Act for the meaning given to "NHS body".

\(^3\) Section 98A of the National Health Service Act 2006 (c.41) ("the 2006 Act") was inserted by section 49(1) of the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). The relevant Directions given by the Secretary of State under section 98A are the Alternative Provider Medical Services Directions 2016 which were signed on 3rd October 2016 and amended on 18th October 2017. They relate to the provision of primary medical services under section...
83(2) of the 2006 Act under an Alternative Provider Medical Services Contract. These Directions are available at: https://www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013. Hard copies may be requested by post from the General Practice Team, Quarry House, Quarry Hill, Leeds, LS2 7UE.

Section 14D was inserted by section 25(1) of the 2012 Act.

Section 83(1) and (2) was substituted by paragraph 30 of Schedule 4 to the 2012 Act.

Section 2A was inserted by section 11 of the 2012 Act and amended by section 116(1) of the Energy Act 2013 (c.22).

Section 2B was inserted by section 12 of the 2012 Act.

Paragraph 12 of Schedule 1 was amended by section 17(12) of the 2012 Act.

Section 111 was amended by section 29(2) of the 2012 Act.

Paragraph 1 of Schedule 1 was amended by section 17(12) of the 2012 Act. Paragraph 2 of Schedule 1 was amended by section 17(4) of that Act. Paragraph 3 of Schedule 1 was amended by paragraph 6 of Schedule 14 to the Health and Social Care Act 2008 (c.14) ("the 2008 Act"). Paragraph 4 of Schedule 1 was amended by section 17(5) of the 2012 Act. Paragraphs 7A and 7B of Schedule 1 were inserted by section 143(1) of the 2008 Act and were amended respectively by section 17(7) and (8) of the 2012 Act.

Section 6C was inserted by section 18(1) of the 2012 Act.

Section 7A was inserted by section 22 of the 2012 Act.

Section 3 was amended by section 13 of the 2012 Act.

Section 3A was inserted by section 14 of the 2012 Act.

Section 3B was inserted by section 15 of the 2012 Act.

Extent

Pt 1 reg. 1A(1)-(8): England, Wales

Law In Force

2.— Application of these Regulations to armed forces bodies

(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.

(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.

Commencement

Pt 1 reg. 2(1)-(3): January 1, 2011

Extent

Pt 1 reg. 2(1)-(3): England, Wales, Scotland
3.— Application and extent

(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.

[(3) In so far as these Regulations are amended by Part 4 of the Amendments Relating to the Provision of Integrated Care Regulations 2019—
   (a) they extend to England and Wales; and
   (b) they apply in relation to England only.
]¹

Notes
¹ Added by Amendments Relating to the Provision of Integrated Care Regulations 2019/248 Pt 4 reg.16 (April 1, 2019)

PART 2

Responsible Officers

4.— Designated bodies

(1) The designation of bodies for the purposes of section 45A of the Act is prescribed as follows.

(2) The bodies listed in Part 1 of the Schedule to these Regulations are designated bodies.

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

Commencement
Pt 2 reg. 4(1)-(3): January 1, 2011

Extent
Pt 2 reg. 4(1)-(3): England, Wales, Scotland
[5.— Duty to nominate or appoint responsible officers

(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.

1 Notes

1 Substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(2) (April 1, 2013)

Commencement
Pt 2 reg. 5(1)-(4): January 1, 2011

Extent
Pt 2 reg. 5(1)-(6): England, Wales, Scotland

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

(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.

Commencement
Pt 2 reg. 6(1)-(3): January 1, 2011

Extent
Pt 2 reg. 6(1)-(3): England, Wales, Scotland

7.— Conditions for nomination or appointment of responsible officers and for remaining as responsible officers

(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.

Commencement
Pt 2 reg. 7(1)-(2): January 1, 2011

Extent
Pt 2 reg. 7(1)-(2): England, Wales, Scotland

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

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.
9.— Nomination of responsible officer by the Secretary of State

(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 [or a sufficient number of responsible officers] \(^1\) 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 [Monitor] \(^2\).

Notes

1 Words inserted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(3) (April 1, 2013)

2 Words substituted by NHS Commissioning Board Authority (Abolition and Transfer of Staff, Property and Liabilities) and the Health and Social Care Act 2012 (Consequential Amendments) Order 2012/1641 Sch.4 para.19 (October 1, 2012)

10.— Connection between designated bodies and medical practitioners

(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—
(za) the designated body is the Faculty of Medical Leadership and Management and the medical practitioner holds the post of either the National Medical Director or National Deputy Medical Director of the Board; [1]

(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
   [ (ia) a Local Education and Training Board and the medical practitioner is a doctor in training who is a member of a foundation or specialty training programme managed by that Board; or ] [3]
   (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;

(aa) where none of the preceding sub-paragraphs apply, the designated body is an integrated care provider where the medical practitioner—
   (i) is employed by an integrated care provider to provide primary medical services; or
   (ii) provides health services under the 2006 Act (which are not primary medical services) for or on behalf of an integrated care provider or is engaged by such a provider to provide such services;

(b) where none of the preceding sub-paragraphs apply, the medical practitioner is on the designated body’s medical performers list or ophthalmic performers list prepared in accordance with—
   (i) regulations 3(1)(a) or 3(1)(c) (as the case may be) of the National Health Service (Performers Lists) (England) Regulations 2013; [8]
   (ii) regulation 3(1)(a) of the National Health Service (Performers Lists) (Wales) Regulations 2004; or
   (iii) regulation 4(1) of the National Health Service (Primary Medical Services Performers Lists) (Scotland) Regulations 2004;

(ba) where none of the preceding sub-paragraphs apply, the designated body is the United Kingdom Health Security Agency 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; [12]

(c) where none of the preceding sub-paragraphs apply, the medical practitioner is employed by the designated body; [13]

(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 responsibility for treating patients in that hospital in accordance with practising privileges for that hospital; ]

[ (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;

(1) 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
(bb) in any other case, the medical practitioner has a prescribed connection with the designated body which is located the shortest distance from the practitioner’s address as registered with the General Council;
(f) where a prescribed connection with more than one designated body arises under paragraph (1)(d) (medical practitioner contracting with a locum agency), the medical practitioner has a prescribed connection with the designated body in respect of which the practitioner carried out most of their clinical practice in the previous calendar year;

(g) in any other case—

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

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

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

(bb) in any other case, the medical practitioner has a prescribed connection with the designated body which is located the shortest distance from the practitioner’s address as registered with the General Council.

(3) Where—

(a) a medical practitioner (“M”) would otherwise have a prescribed connection with a designated body;

(b) M has a prescribed connection with a designated body under regulations made under section 45A of the Act in relation to Northern Ireland; and

(c) M carries out most of M’s clinical practice in Northern Ireland,

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

(4) Where a medical practitioner is on a designated body’s medical performers list in accordance with paragraph (1)(b) and is also employed by an armed forces body—

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

(b) if there is no significant difference in the amount of clinical practice which the practitioner carries out for each designated body, the prescribed connection is with the armed forces body.

(5) For the purposes of paragraphs (2)(c)(ii), (2)(e)(ii)(bb) and (2)(g)(ii)(bb), the location of a designated body is the address of its principal office.

Notes

1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(4)(a) (April 1, 2013)

2 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.

3 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(4)(b) (April 1, 2013)

4 Local Education and Training Boards are committees of Health Education England.

5 Added by Amendments Relating to the Provision of Integrated Care Regulations 2019/248 Pt 4 reg.17 (April 1, 2019)

6 Words substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(4)(c)(i) (April 1, 2013)

7 Words inserted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(4)(c)(ii) (April 1, 2013)
11.— Responsibilities of responsible officers: prescribed connection under regulation 10

(1) Subject to paragraph (6), the responsible officer for a designated body has the following responsibilities relating to the evaluation of the fitness to practise of every medical practitioner who has a prescribed connection with that body by virtue of regulation 10.

(2) The responsibilities referred to in paragraph (1) are—
   (a) to ensure that the designated body carries out regular appraisals on medical practitioners in accordance with paragraph (3);
   (b) to establish and implement procedures to investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the designated body or arising from any other source;
   (c) where appropriate, to refer concerns about the medical practitioner to the General Council;
   (d) where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Council, to monitor compliance with those conditions or undertakings;
   (e) to make recommendations to the General Council about medical practitioners' fitness to practise;
   (f) to maintain records of practitioners' fitness to practise evaluations, including appraisals and any other investigations or assessments.

(3) The responsible officer must ensure that appraisals carried out under paragraph (2)(a) involve obtaining and taking account of all available information relating to the medical practitioner's fitness
to practise in the work carried out by the practitioner for the designated body, and for any other body, during the appraisal period.

(4) Procedures under paragraph (2)(b) must include provision for the medical practitioner's comments to be sought and taken into account where appropriate.

(5) Responsible officers must co-operate with the General Council and any of its committees, or any persons authorised by the General Council, in connection with the exercise by them of any of their functions under Part 3A or 5 of the Act.

[(6) Where a responsible officer is nominated or appointed in accordance with regulation 5(2) (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.]¹

Notes

¹ Substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(5) (April 1, 2013)

Commencement

Pt 2 reg. 11(1)-(6): January 1, 2011

Extent

Pt 2 reg. 11(1)-(6): England, Wales, Scotland

Law In Force

[ 12.— Connection between designated bodies and medical practitioners who are responsible officers

(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

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Body of which a registered medical practitioner is a responsible officer)</td>
<td>(Body with which there is a prescribed connection)</td>
</tr>
<tr>
<td>3. Local Education and Training Boards.</td>
<td>3. Health Education England³.</td>
</tr>
<tr>
<td>4. Any body in England not falling within the preceding entries except—</td>
<td>4. the Board.</td>
</tr>
<tr>
<td>(a) the Board.</td>
<td></td>
</tr>
<tr>
<td>(b) Faculty of Medical Leadership and Management.</td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
</tr>
<tr>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>(Body of which a registered medical practitioner is a responsible officer)</td>
<td>(Body with which there is a prescribed connection)</td>
</tr>
<tr>
<td>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.</td>
<td>5. the Faculty of Medical Leadership and Management.</td>
</tr>
<tr>
<td>6. The Board in respect of a medical practitioner appointed or nominated under regulation 5(2) and not falling in the preceding entry.</td>
<td>6. the Board.</td>
</tr>
<tr>
<td>7. Any body in Scotland.</td>
<td>7. the Scottish Ministers.</td>
</tr>
<tr>
<td>8. Any body in Wales.</td>
<td>8. the Welsh Ministers.</td>
</tr>
</tbody>
</table>

(2) A medical practitioner who is a responsible officer for—
   (a) the Department of Health [ and Social Care ]\(^1\);  
   (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.  

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(6) (April 1, 2013)</td>
</tr>
<tr>
<td>2 Words inserted by Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018/378 Sch.1(2) para.20(t) (April 11, 2018)</td>
</tr>
<tr>
<td>3 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).</td>
</tr>
</tbody>
</table>

Commencement
Pt 2 reg. 12(1)-(3)(c): January 1, 2011

Extent
Pt 2 reg. 12(1)-(3)(c): England, Wales, Scotland

Law In Force

13.— Responsibilities of responsible officers: prescribed connection under regulation 12

(1) Subject to paragraph (6), the responsible officer for a designated body has the following responsibilities relating to the evaluation of the fitness to practise of every medical practitioner who has a prescribed connection with that body by virtue of regulation 12.

(2) The responsibilities referred to in paragraph (1) are—
   (a) to take all reasonably practicable steps to ensure that the medical practitioner undergoes regular appraisals in accordance with paragraph (3);
(b) to take all reasonably practicable steps to investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the body for whom the medical practitioner is the responsible officer, or arising from any other source;
(c) where appropriate, to refer concerns about the practitioner to the General Council;
(d) where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Council, to monitor compliance with those conditions or undertakings;
(e) to make recommendations to the General Council about the medical practitioner's fitness to practise;
(f) to maintain records of the medical practitioner's fitness to practise evaluations, including appraisals and any other investigations or assessments.

(3) The responsible officer must take reasonably practicable steps to ensure that appraisals under paragraph (2)(a)—
(a) are carried out by the body for whom the medical practitioner is the responsible officer; and
(b) involve obtaining and taking account of all available information relating to the medical practitioner's fitness to practise in the work carried out by the practitioner during the appraisal period.

(4) Procedures under paragraph (2)(b) must include provision for the medical practitioner's comments to be sought and taken into account where appropriate.

(5) Responsible officers must co-operate with the General Council and any of its committees, or any persons authorised by the General Council, in connection with the exercise by them of any of their functions under Part 3A or 5 of the Act.

[ (6) Where a responsible officer is nominated or appointed in accordance with regulation 5(2) (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. ]

Notes
1 Substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(7) (April 1, 2013)

Commencement
Pt 2 reg. 13(1)-(6): January 1, 2011

Extent
Pt 2 reg. 13(1)-(6): England, Wales, Scotland

Law In Force

14.— Provision of resources to responsible officers

(1) Subject to paragraph (2), each designated body must provide the responsible officer [ or responsible officers (as the case may be) ]\(^1\) nominated or appointed for that body with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under regulations 11 and 13.
(2) Where the designated body does not employ its responsible officer, the body must provide the resources referred to in paragraph (1) to—
   (a) where the responsible officer is employed, the employer of the officer; and
   (b) in any other case, the responsible officer.

(3) Where a medical practitioner has a prescribed connection with a designated body by virtue of sub-paragraph (d), (e), (f), (g) or (h) of regulation 10(1), the medical practitioner must provide the designated body with sufficient funds necessary to enable the responsible officer nominated or appointed for that body to discharge their responsibilities under regulation 11 relating to that medical practitioner.

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

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Notes
1 Words inserted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.3(8) (April 1, 2013)

Commencement
Pt 2 reg. 14(1)-(4): January 1, 2011

Extent
Pt 2 reg. 14(1)-(4): England, Wales, Scotland

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15. Duty to have regard to guidance
In discharging their responsibilities under regulations 11 and 13, responsible officers shall have regard to the following—
   (a) guidance given by the Secretary of State in accordance with section 45C(2) of the Act; and
   (b) guidance given by the General Council, including Good Medical Practice and guidance on fitness to practise procedures, to the extent that it relates to the nomination or appointment of responsible officers or their prescribed responsibilities.

Commencement
Pt 2 reg. 15(a)-(b): January 1, 2011

Extent
Pt 2 reg. 15(a)-(b): England, Wales, Scotland
PART 3

Additional Responsibilities of Responsible Officers: England

Law In Force

16.— Additional responsibilities of responsible officers: prescribed connection under regulation 10

(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 to the extent that the medical practitioner concerned is practising in England.

(2) In relation to the entry by the designated body into contracts of employment or for the provision of services with medical practitioners, the responsible officer must—
   (a) ensure that medical practitioners have qualifications and experience appropriate to the work to be performed;
   [ (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) ensure that appropriate references are obtained and checked;
   (c) take any steps necessary to verify the identity of medical practitioners;
   [ (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; ]
   (e) maintain accurate records of all steps taken in accordance with sub-paragraphs (a) to (d).

(3) 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) ensure that the designated body takes steps to address any such issues.

(4) 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;
   (d) consider the need for further monitoring of the 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;
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

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.

Notes

1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.4(2)(a) (April 1, 2013)
2 Substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.4(2)(b) (April 1, 2013)
3 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.

Commencement
Pt 3 reg. 16(1)-(4)(i): January 1, 2011

Extent
Pt 3 reg. 16(1)-(2)(a), (2)(b)-(4)(i): England, Wales (applies in relation to England only)
Pt 3 reg. 16(2)(aa): England, Wales

17.— Additional responsibilities of responsible officers: prescribed connection under regulation 12

(1) Where a responsible officer has responsibilities under regulation 13 in respect of a medical practitioner who has a prescribed connection with a designated body in accordance with regulation 12, the responsible officer has the following additional responsibilities to the extent that the medical practitioner concerned is practising in England.

(2) The responsible officer must ensure that the medical practitioner has established systems and procedures which will enable them to carry out their responsibilities under regulation 16(2) effectively.

(3) 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.

(4) 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 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.

Commencement
Pt 3 reg. 17(1)-(4)(i): January 1, 2011

Extent
Pt 3 reg. 17(1)-(4)(i): England, Wales (applies in relation to England only)

18. Duty to have regard to guidance
In discharging their responsibilities under regulations 16 and 17, responsible officers must have regard to the following—

(a) guidance given by the Secretary of State in accordance with section 120(6) of the Health and Social Care Act 2008; and
(b) guidance given by the National Clinical Assessment Service division of the National Health Service Litig ation Authority\(^2\), 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). \(^1\)

Notes

1 Reg.18(b) and (c) substituted for reg.18(b) by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.4(3) (April 1, 2013)

2 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).

Commencement

Pt 3 reg. 18(a)-(b): January 1, 2011

Extent

Pt 3 reg. 18(a)-(b): England, Wales (applies in relation to England only)

Pt 3 reg. 18(c): England, Wales

Law In Force

19.— Provision of resources to responsible officers

(1) Each designated body must provide its responsible officer \([\text{ or responsible officers (as the case may be)}]\)\(^1\) with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under regulations 16 and 17.

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

(a) where the responsible officer is employed, the employer of the officer; and

(b) in any other case, the responsible officer.

(3) Where a medical practitioner has a prescribed connection with a designated body by virtue of sub-paragraph (d), (e), (f), (g) or (h) of regulation 10(1), the medical practitioner must provide the designated body with sufficient funds necessary to enable the responsible officer nominated or appointed for that body to discharge their responsibilities under regulation 16 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.

Notes

1 Words inserted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.4(4) (April 1, 2013)
Commencement
Pt 3 reg. 19(1)-(4): January 1, 2011

Extent
Pt 3 reg. 19(1)-(4): England, Wales (applies in relation to England only)

Signed by authority of the Secretary of State for Health.
Anne Milton
Parliamentary Under-Secretary of State,
Department of Health
24th November 2010

SCHEDULE
Designated Bodies

PART 1
Designated bodies

Regulation 4(2)

Notes
1 Words substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.5(2) (April 1, 2013)

Commencement
Sch. 1(1) para. 1: January 1, 2011

Extent
Sch. 1(1) para. 1: England, Wales, Scotland
2. Local Health Boards.

Commencement
Sch. 1(1) para. 2: January 1, 2011

Extent
Sch. 1(1) para. 2: England, Wales, Scotland

[2A. Integrated care providers.
]¹

Notes
¹ Added by Amendments Relating to the Provision of Integrated Care Regulations 2019/248 Pt 4 reg.18 (April 1, 2019)

Extent
Sch. 1(1) para. 2A: England, Wales

3. [National Health Service trusts other than Ambulance Trusts]¹.

Notes
¹ Words substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.5(3) (April 1, 2013)

Commencement
Sch. 1(1) para. 3: January 1, 2011

Extent
Sch. 1(1) para. 3: England, Wales, Scotland

[4. NHS foundation trusts other than Ambulance Trusts]¹.
Notes

1 Words substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.5(4) (April 1, 2013)

Commencement

Sch. 1(1) para. 4: January 1, 2011

Extent

Sch. 1(1) para. 4: England, Wales, Scotland

Repealed

5. […]¹

Notes

¹ Revoked by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.5(5) (April 1, 2013)

Law In Force


Commencement

Sch. 1(1) para. 6: January 1, 2011

Extent

Sch. 1(1) para. 6: England, Wales, Scotland

Law In Force

7. The Department of Health [ and Social Care]¹.

Notes

¹ Words inserted by Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018/378 Sch.1(2) para.20(t) (April 11, 2018)

Commencement

Sch. 1(1) para. 7: January 1, 2011
Extent
Sch. 1(1) para. 7: England, Wales, Scotland

Law In Force

8.
The Scottish Ministers.

Commencement
Sch. 1(1) para. 8: January 1, 2011

Extent
Sch. 1(1) para. 8: England, Wales, Scotland

Law In Force

9.
The Welsh Ministers.

Commencement
Sch. 1(1) para. 9: January 1, 2011

Extent
Sch. 1(1) para. 9: England, Wales, Scotland

Law In Force

10.
Postgraduate medical deaneries in England and Wales.

Commencement
Sch. 1(1) para. 10: January 1, 2011

Extent
Sch. 1(1) para. 10: England, Wales, Scotland

Law In Force

11.
Any Scottish training governance body.
Commencement
Sch. 1(1) para. 11: January 1, 2011

Extent
Sch. 1(1) para. 11: England, Wales, Scotland

Law In Force

12. The Royal Navy.

Commencement
Sch. 1(1) para. 12: January 1, 2011

Extent
Sch. 1(1) para. 12: England, Wales, Scotland

Law In Force

13. The regular army within the meaning of section 374 of the Armed Forces Act 2006.

Commencement
Sch. 1(1) para. 13: January 1, 2011

Extent
Sch. 1(1) para. 13: England, Wales, Scotland

Law In Force


Commencement
Sch. 1(1) para. 14: January 1, 2011

Extent
Sch. 1(1) para. 14: England, Wales, Scotland
[14A. Local Education and Training Boards.]

Notes
1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.5(6) (April 1, 2013)

Extent
Sch. 1(1) para. 14A: United Kingdom

[14B. Pathology Delivery Board.]

Notes
1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.5(6) (April 1, 2013)

Extent
Sch. 1(1) para. 14B: United Kingdom

PART 2

Designated bodies which employ or contract with medical practitioners

Regulation 4(3)

15. Special Health Boards.

Commencement
Sch. 1(2) para. 15: January 1, 2011

Extent
Sch. 1(2) para. 15: England, Wales, Scotland
16. Special Health Authorities.

Commencement
Sch. 1(2) para. 16: January 1, 2011

Extent
Sch. 1(2) para. 16: England, Wales, Scotland

17. The Common Services Agency for the Scottish Health Service¹.

Notes
¹ The Common Services Agency is a non-departmental public body, known as the NHS National Services Scotland. See http://www.nhsnss.org/index.php?id=2.

Commencement
Sch. 1(2) para. 17: January 1, 2011

Extent
Sch. 1(2) para. 17: England, Wales, Scotland

18. Bodies which provide independent health care services within the meaning of [section 10F(1)(a) to (d) of the National Health Service (Scotland) Act 1978]¹.

Notes
¹ Words substituted by Public Services Reform (Scotland) Act 2010 (Consequential Modifications of Enactments) Order 2011/2581 Sch.2(2) para.67 (October 28, 2011)

Commencement
Sch. 1(2) para. 18: January 1, 2011

Extent
Sch. 1(2) para. 18: England, Wales, Scotland

Commencement
Sch. 1(2) para. 19: January 1, 2011

Extent
Sch. 1(2) para. 19: England, Wales, Scotland

20. The following locum agencies—

   (a) limited companies with shares owned wholly by the Secretary of State for Health, which are concerned with the contracting of locum doctors¹; and
   [(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 sector³. ]²

Notes
¹ Currently the sole member of this class is NHS Professionals Ltd, company number 06704614; see also www.nhsprofessionals.nhs.uk.
² Substituted by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.6(2) (April 1, 2013)
³ Contract reference number RM1570: responsibility for this agreement is with the Government Procurement Service, an executive agency of the Cabinet Office.

Commencement
Sch. 1(2) para. 20(a)-(b): January 1, 2011

Extent
Sch. 1(2) para. 20(a)-(b): England, Wales, Scotland

22. Any body whose principal office is located in the United Kingdom and whose President or Dean is a member of the Academy of Medical Royal Colleges.

23. Bodies which have functions under the Act in relation to the regulation of medical practitioners.\(^1\)

Notes
\(^1\) These bodies are the General Medical Council and the Office of the Health Professions Adjudicator.
Commencement
Sch. 1(2) para. 24: January 1, 2011

Extent
Sch. 1(2) para. 24: England, Wales, Scotland

Law In Force

25.
Any organisation engaged in the provision of treatment for disease, disorder or injury by or under the supervision of a medical practitioner.

Commencement
Sch. 1(2) para. 25: January 1, 2011

Extent
Sch. 1(2) para. 25: England, Wales, Scotland

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

Notes
1  Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.6(3) (April 1, 2013)

Extent
Sch. 1(2) para. 25A: United Kingdom

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

Notes
1  Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.6(3) (April 1, 2013)
[25C. Ambulance Trusts.]

Notes
1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.6(3) (April 1, 2013)

[25D. The British College of Aesthetic Medicine.]

Notes
1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.6(3) (April 1, 2013)

[25E. The Faculty of Homeopathy.]

Notes
1 Added by Medical Profession (Responsible Officers) (Amendment) Regulations 2013/391 reg.6(3) (April 1, 2013)
26.—

(1) Any organisation which carries out surgical procedures (including any pre-operative and post-operative care associated with such procedures) undertaken by or under the supervision of a medical practitioner who is employed by, or who contracts with, that organisation 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.

Commencement

Sch. 1(2) para. 26(1)-(2)(c): January 1, 2011

Extent

Sch. 1(2) para. 26(1)-(2)(c): England, Wales, Scotland

27.—

(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.
28. Any organisation which is engaged in the analysis and reporting of the results of the procedures referred to in paragraph 27.

29. 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.

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

32. A body engaged in the provision of residential accommodation together with nursing care.

33. A body engaged in the provision of first aid treatment and established for that purpose.
34. 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.

Commencement
Sch. 1(2) para. 34: January 1, 2011

Extent
Sch. 1(2) para. 34: England, Wales, Scotland

35. 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.

Notes
1 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 I and by S.I. 2007/1522.

Commencement
Sch. 1(2) para. 35: January 1, 2011

Extent
Sch. 1(2) para. 35: England, Wales, Scotland

36. 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.

Commencement
Sch. 1(2) para. 36: January 1, 2011

Extent
Sch. 1(2) para. 36: England, Wales, Scotland
37. 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.

Commencement
Sch. 1(2) para. 37: January 1, 2011

Extent
Sch. 1(2) para. 37: England, Wales, Scotland

38. 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.

Commencement
Sch. 1(2) para. 38: January 1, 2011

Extent
Sch. 1(2) para. 38: England, Wales, Scotland

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 certain other bodies, and will have responsibilities relating to the evaluation of the fitness to practise of doctors who work in the organisation. The Regulations come into force on 1st January 2011.
Part 1 of the Regulations contains general provisions: regulation 1 contains citation, commencement date and interpretation provisions; regulation 2 contains interpretation provisions for the armed forces, and regulation 3 deals with the application of the Regulations.

Part 2 of the Regulations applies to England, Scotland and Wales. This Part deals with the appointment of ROs and their responsibilities under the Act.

Regulation 4 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 4(2) and Part 1 of the Schedule list bodies that are always required to have ROs, for example NHS hospitals; regulation 4(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, Government departments. Government-owned locum agencies (NHS Professionals Ltd currently being the sole such agency in the class described in paragraph 20(a)) are designated bodies; other locum agencies in England and Wales are designated bodies only if they are on the NHS Purchasing and Supply Agency’s framework agreement (paragraph 20(b) of the Schedule); this agreement can be viewed at the following website: http://www.buyingsolutions.gov.uk/healthcms/Productsandservices/Agencystaffandoutsourcedservices/temporarystaff/Medicallocums/.

Regulation 5 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 10).

Regulation 6 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 7 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 8 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 9 provides that the Secretary of State may nominate an RO for a designated body when the body has failed to do so, or has appointed someone unsuitable. The Secretary of State must consult the Scottish or Welsh Ministers, as applicable, before making such an appointment in respect of an NHS body in Scotland or Wales, and must consult the independent regulator (Monitor) before making such an appointment in relation to an NHS Foundation Trust.

Regulation 10 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 11. Doctors in training in England and Wales are linked to the postgraduate deanery that is responsible for their training; doctors in training in Scotland are linked to a Scottish training governance body (NHS Education for Scotland currently being the sole body falling within that class). Where a doctor is on the performers list of a primary care organisation, that organisation (a Primary Care Trust in England, a Health Board in Scotland or a Local Health Board in Wales) will be the designated body for the doctor, except for doctors in the armed forces who will be linked to the organisation where they do most of their work. Where the doctor is an employee of a designated body (and is not a trainee or on a performers list), the employing organisation will be the designated body for that doctor. Doctors working as locums
will be linked to their locum agency if that agency is NHS Professionals Ltd, or is on an approved list (the NHS PASA framework) in England and Wales; other locums will be linked to their nearest Primary Care Trust, Health Board or Local Health Board. 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 and the doctor is a member of one of certain designated professional bodies, the doctor will be linked to that body. A doctor who is a member of the Independent Doctors' Federation ("the IDF") will be linked to that body if none of the preceding provisions applies: the IDF is a body which represents doctors who work outside other structures, and it sought designation under the Regulations during consultations with the Department of Health. The regulation also sets out an order of priority in the event that the doctor could be connected to more than one body.

Regulation 11 sets out the responsibilities of ROs in relation to doctors who are connected with the designated body under regulation 10. 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 12 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 13 makes provision similar to regulation 11 in respect of ROs' responsibilities in relation to doctors who are connected with the designated body under regulation 12.

Regulation 14 contains a requirement for designated bodies and medical practitioners to provide resources to ROs, and regulation 15 contains a duty for ROs to have regard to guidance.

Part 3 of the Regulations applies to England only. This Part contains additional responsibilities for ROs under section 120 of the Health and Social Care Act 2008.

Regulation 16 sets out the additional responsibilities for ROs in England in respect of the doctors for whom they are responsible under regulation 10; these include carrying out pre-employment checks on doctors, monitoring doctors' conduct and performance, and investigating and taking appropriate action to deal with concerns about doctors. Regulation 17 makes similar provision for ROs' responsibilities in relation to doctors for whom they are responsible under regulation 12.

Regulation 18 contains a duty for ROs to have regard to guidance, and regulation 19 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, Quarry House, Quarry Hill, Leeds LS2 7UE; see also http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment.
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