

EXPLANATORY MEMORANDUM TO
THE MEDICAL PROFESSION (RESPONSIBLE OFFICERS) (AMENDMENT)
REGULATIONS 2013

2013 No. 391

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument amends the Medical Profession (Responsible Officer) Regulations 2010 (“the 2010 Regulations”). The 2010 Regulations established the role of the responsible officer in the medical profession and set out the requirements and functions of the role, which primarily is concerned with the evaluation of a doctor’s fitness to practise.

2.2 The main purpose for amending the 2010 Regulations is to make consequential changes to take account of the new NHS architecture, as set out in the Health and Social Care Act 2012 (“the Act”).¹ The instrument also enables more doctors to be evaluated with regard to their fitness to practise and, for doctors practising in England, to ensure that those doctors have sufficient knowledge of English language to perform their work when they are appointed to an organisation.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 The amendments relating to language knowledge form part of the Government commitment to ensure that foreign health care professionals have the necessary language skills to ensure that patients are not put at risk through an inability to communicate effectively. This commitment was set out in the Coalition Agreement². The issue was also raised in the GMC’s annual accountability report by the Health Select Committee³ and in its response the Government gave a commitment to develop a proportionate new system of checks through enhanced duties on responsible officers to ensure that any person appointed to a medical post has the necessary skills for the role, before they take up post. These amendments only apply to doctors practising in England as they relate to clinical governance functions which are free standing provisions under section 120 of the Health and Social Care Act 2008.

¹ The Health and Social Care Act 2012 (2012 c.7), available at:
<http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>

²The Coalition: Our programme for government available at:
http://www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_187876.pdf

³ Health Committee - Fifteenth Report is available at:
<http://www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1699/169902.htm>

4.2 The process for the revalidation of doctors has now been finalised and the provisions came into force on 3rd December 2012⁴. The amendments, which prescribe additional designated bodies and which make additional connections between designated bodies and doctors, will enable doctors connected to those bodies to be evaluated by the responsible officer as part of the revalidation process.

4.3 The changes which amend the framework of the 2010 Regulations are necessary as a consequence of the wider reforms to the NHS structure established through the Health and Social Care Act 2012. The White Paper *Equity and Excellence: Liberating the NHS*⁵ set out the Government's vision for health services which formed the basis for the 2012 Act.

5. Territorial Extent and Application

5.1 Amendments to Parts 1 and 2 of the 2010 Regulations apply to England, Wales and Scotland. Amendments to Part 3 (additional responsibilities of responsible officers) apply to England only.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

The 2010 Regulations and the Health and Social Care Act 2008

7.1 The White Paper *Trust, Assurance, and Safety* set out that doctors will relate formally to a responsible officer in the organisation where they work. The White Paper envisaged that this officer would liaise with the General Medical Council over the fitness to practise of individual doctors and oversee local systems for dealing with issues of doctors' performance and conduct. The resulting primary legislation, the Health and Social Care Act 2008⁵, made provision, amongst other things, for the role of the responsible officer.

7.2 The Health and Social Care Act 2008 made provision (by the insertion of new powers in the Medical Act 1983) for designated bodies to nominate or appoint a responsible officer with responsibilities relating to the evaluation of the fitness to practise of doctors with a prescribed connection to the body.

7.3 Section 120 of the Health and Social Care Act 2008 made provision for additional responsibilities of responsible officers in England, Wales, and Northern Ireland relating to local systems of clinical governance.

7.4 The 2010 Regulations came into force on 1st January 2011 which established the role of the responsible officer and made provision for designated bodies to nominate or appoint a responsible officer. From that date, designated organisations were required to nominate or appoint a responsible officer with statutory functions

⁴ The General Medical Council (Licence to Practise and Revalidation) Regulations Order of Council 2012 S.I 2012/2685.

⁵ *Equity and Excellence: Liberating the NHS*, Department of Health, 2010,

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353

relating to the evaluation of the fitness to practice and monitoring of the conduct and performance of doctors with whom the body had a connection. The 2010 Regulations also made provision for additional responsibilities to be undertaken by responsible officers in England only relating to functions of clinical governance.

The Health and Social Care Act 2012

7.5 The White Papers, *Equity and Excellence: Liberating the NHS* and *Healthy Lives, Healthy People: Our Strategy for Public Health in England*⁶, set out a series of reforms for the delivery of healthcare and public health. These reforms were given a statutory basis in the Act. The Act abolishes Primary Care Trusts (PCTs) and Strategic Health Authorities from 31 March 2013. The Act sets out a new structure where responsibility for local clinical commissioning rests with clinical commissioning groups (“CCGs”). CCGs will be supported and overseen by the NHS Commissioning Board (“the Board”). The Act also transfers public health functions from PCTs to local authorities.

NHS Commissioning Board

7.6 The amending regulations prescribe the NHS Commissioning Board as a designated body under the 2010 Regulations. The policy is to provide the NHS Commissioning Board with the flexibility to appoint a number of responsible officers necessary to ensure that each responsible officer has the capacity to carry out their responsibilities under the Regulations. Given the size of the NHS Commissioning Board, it was considered necessary to provide the Board with such flexibility to adapt to changing circumstances which may arise.

7.7 There are specific groups of doctors that are currently connected to PCTs and SHAs under the 2010 Regulations and therefore it is necessary to make provision for these bodies which will be abolished on 31st March 2013. The amending instrument seeks to replace these connections with the NHS Commissioning Board so that doctors who had a connection with either of these bodies will now be connected to the Board.

Faculty of Medical Leadership and Management

7.8 Concerns were raised about possible conflicts of interest at the Commissioning Board. To alleviate this risk, this instrument connects the NHS Medical Director and Deputy Directors with the Faculty of Medical Leadership and Management, which will be responsible for evaluating those doctors’ fitness to practise. The Faculty will also have a connection for its members that have no other connection.

Health Education England

7.9 The Department of Health has set out a new approach to education and training in *From Design to Delivery*⁷. Currently, the post graduate deaneries in England and

⁶ Healthy Lives, Healthy People: Our Strategy for Public Health in England, Department of Health, 2012, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127424.pdf

⁷ Liberating the NHS: Developing the Healthcare Workforce: From design to delivery, Department of Health, 2012, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132087.pdf

Wales are responsible for the education and training of trainee doctors. However, this responsibility will transfer to Health Education England (“HEE”) which will provide national leadership and oversight on strategic planning and development of the health and public health workforce, and allocate education and training resources. Local Education and Training Boards, a committee of HHE, will be responsible for leading local healthcare education and training and the associated expenditure. This instrument amends the connection for trainee doctors connected to post graduate deaneries in England to Local Education and Training Boards.

Public Health

7.10 In public health, the reforms will see local authorities taking the lead for improving health and co-ordinating local efforts to protect the public’s health and wellbeing, and ensuring health services effectively promote population health. Local political leadership will be central to making this work. A new executive agency, Public Health England (PHE), will:

- deliver services;
- lead for public health; and,
- support the development of the specialist and wider public health workforce.

7.11 As an executive agency of the Government, Public Health England will qualify as a designated body under paragraph 19 of the 2010 Regulations. Local authority doctors have been connected to Public Health England who will be responsible for evaluating their fitness to practise.

Responsible Officers’ Connections to Their Responsible Officer

7.12 Regulation 12 makes the connection for a responsible officer’s own responsible officer. Changes to this provision were required to reflect the new NHS architecture and the consequential changes required to the responsible officers framework.

Language skills

7.13 There have been persistent concerns about the skills and competencies of some foreign doctors, particularly in respect of language skills. It is for this reason that the Amendment Regulations make it explicit that responsible officers’ have a responsibility to ensure that medical practitioners have sufficient knowledge of English language to perform their work when they join an organisation.

Additions to the designated bodies

7.14 The instrument designates additional organisations and groups of organisations. The organisations either represent doctors who work outside managed organisations or organisations that employ doctors but are not directly responsible for the care and treatment of patients. The Department of Health was approached by these organisations and considered whether they had appropriate systems of governance in place including systems for appraising doctors, handling complaints and investigating concerns. The organisations are: Pathology Delivery Board, Resident Medical Officer

Organisations, Medical Defence Organisations British College of Aesthetic Medicine and The Faculty of Homeopathy.

Updates to terminology

7.15 The National Clinical Assessment Service (NCAS), currently a division of the National Institute for Health and Clinical Excellence, will become a division of the NHS Litigation Authority on 1 April 2013. This instrument amends references to NCAS.

7.16 The NHS Purchasing and Supply Framework Agreement for the procurement of secondary care locum doctors has been re-tendered by the Government Procurement Service. This instrument amends references to that agreement.

Ambulance Trusts

7.17 As NHS Trusts, NHS Ambulance Trusts were designated under Part 1 of the Schedule and had to nominate or appoint a responsible officer even if they did not employ any doctor. This amending instrument makes changes so that only those Trusts that employ a doctor have to nominate or appoint a responsible officer.

8. Consultation outcome

8.1 A public consultation on the policy changes ran between April 2012 and July 2012. There were 88 responses to the consultation. The responses were generally supportive of the changes proposed. However, there were concerns about the potential for conflicts of interest in the Board.

8.2 The proposal for the GMC to annotate their register to confirm suitability for a doctor's first post in England and language competence for that post has not been continued. On further consideration there was insufficient benefit to outweigh the practical difficulties of the annotation being applied to the register for England only, and not Northern Ireland, Scotland and Wales. There is already an existing duty in Part 2 of the regulations to refer concerns in relation to fitness to practice and to cooperate with the GMC which includes where there are language concerns. .

8.3 As a result of these concerns the Department:

- introduced an external scrutiny of the most senior doctors in the Commissioning Board by the Faculty of Medical Leadership and Management; and
- amended the proposals on language checking to ensuring that designated bodies assured themselves that doctors they are appointing have an appropriate knowledge of English to enable them to communicate with patients and other professionals.

The Department's response document to the consultation is available on the Department's website⁸.

⁸ A consultation on draft amendment regulations and response to the policy consultation "Responsible officers in the new health architecture", available at:

8.4 The second public consultation was held between December 2012 and January 2013, this time in relation to the draft Amendment Regulations. The audience was the same as for the earlier consultation. There were 27 responses. These raised no further issues.

9. Guidance

9.1 The Department has published revised non statutory guidance alongside this instrument. The document is designed to provide guidance to all doctors, doctors taking on the role of responsible officer, and the organisations designated to nominate or appoint a responsible officer. The guidance will also be relevant to doctors who work in different settings and across a number of organisations to understand which responsible officer they relate to under the regulations. A copy of the guidance is available on the Department's website.

10. Impact

10.1 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk. The Assessment considers the impact of the change of policy introducing the responsible officer's obligations in relation to language skills.

11. Regulating small business

11.1 The legislation applies to small business. The main impact is limited to those organisations that have sought to be included in the legislation.

12. Monitoring & review

12.1 The amendments introduced by the instrument aim to ensure the aims of the 2010 Regulations to improve local systems of assuring good medical practice and to bridge the regulatory gap between local healthcare organisations and the General Medical Council can be met.

12.2 A measurable outcome will be that the system of responsible officers continues to be in place and that the responsible officers are supported through networks run through the NHS Commissioning Board.

13. Contact

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