

EXPLANATORY MEMORANDUM TO
THE MEDICAL PROFESSION (RESPONSIBLE OFFICERS) REGULATIONS 2010

2010 No. [XXXX]

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 The purpose of this instrument is to establish the role of the responsible officer, who will be concerned with the evaluation of doctors' performance. Organisations designated under these regulations will have a duty to appoint a senior doctor to the role of responsible officer. The responsible officer will have duties relating to the evaluation of the fitness to practise of doctors in the organisation, and in England will have additional functions relating to the monitoring of the conduct and performance of doctors.

2.2 These new regulations are designed to help doctors and the organisations where they work to further improve the quality of care provided to patients. They seek to raise the already high standards of the overwhelming majority of professionals, whilst ensuring that the small number of staff who are not able to meet those standards are swiftly identified and then dealt with fairly and effectively and, where appropriate, are supported to get back on track.

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

3.1. None

4. Legislative Context

4.1 This instrument relates to the wider reform of the regulation of healthcare professionals to assure good medical practice following the Chief Medical Officer's report of inconsistencies in local arrangements in *Good Doctors, Safer Patients*, July 2006¹. The instrument is made under powers in the Medical Act 1983 as amended by the Health and Social Care Act 2008, and some additional powers in that 2008 Act.

4.2 Since November 2009 a doctor must have held a licence to practise medicine. It is planned that this licence should be renewed every 5 years in a process known as revalidation. The details of the revalidation process have not yet been finalised, but it is envisaged that a doctor's responsible officer will make a recommendation to the General Medical Council on the doctor's fitness to practise as part of the revalidation process. The General Medical Council has

¹ Good Doctors, Safer Patients, Department of Health, 14 July 2006
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232

recently held a public consultation on the system of revalidation² and they will determine the revalidation process following the outcome of this consultation. The Department of Health is running ten pilots in England that will examine the process of revalidation and the information that needs to be collected through the appraisal process and how this will support recommendations on fitness to practise to the General Medical Council.

- 4.3 These regulations give senior doctors in certain organisations (designated bodies) functions for specified doctors that will ensure doctors are regularly appraised and where there are concerns about a doctor's fitness to practise they are investigated and, where appropriate, referred to the General Medical Council. In England, where the concerns are below the level that the General Medical Council considers a fitness to practise issue, responsible officers will investigate, identify the cause and take the appropriate action to bring the doctor back on track. This policy should achieve an increase in public and professional confidence in the regulation of doctors.
- 4.4 Responsible officers are being introduced now, ahead of the revalidation process, to give them the necessary time and training to prepare for supporting the new process within their organisations.

5. Territorial Extent and Application

- 5.1 Parts 1 and 2 of the regulations apply to England and Wales and Scotland. Part 3 (additional responsibilities of responsible officers) applies to England only.

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Public Health (Anne Milton MP) has made the following statement regarding Human Rights:

“In my view the provisions of the Medical Profession (Responsible Officers) Regulations 2010 are compatible with the Convention rights.”

7. Policy background

- *What is being done and why*

- 7.1 Following the Shipman Inquiry, the Chief Medical Officer undertook a review of the arrangements in place for medical regulation. His report *Good Doctors, Safer Patients* in July 2006 identified inconsistencies in the way organisations managed concerns about doctors and particularly when they were referred to the General Medical Council. This was described as a 'regulatory gap'. The report set out proposals to strengthen the systems for assuring good medical practice and protecting patients.

² Revalidation: The Way Ahead, The General Medical Council, March 2010 <http://www.gmc-uk.org/doctors/licensing/5786.asp>

- 7.2 A public consultation³ was held from July 2006 to November 2006 on the proposals set out in *Good Doctors, Safer Patients* and received over 2000 responses, the majority of which were supportive of the proposals for change in healthcare professional regulation. This consultation informed the programme of reform set out in the Government's White Paper *Trust, Assurance, and Safety: The Regulation of Healthcare Professionals in the 21st Century* in July 2007⁴.
- 7.3 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. This instrument establishes this responsible officer role.
- 7.4 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. This instrument sets out these responsibilities for England, Wales and Scotland. The organisations that this instrument designates in having a duty to nominate or appoint a responsible officer can be broadly summarised as:
- organisations that provide healthcare;
 - organisations that set standards and policy for the delivery of healthcare; and
 - some specialist organisations which employ or contract with doctors.
- The instrument sets out the prescribed connections between individual doctors and the organisation which appoints the doctor's responsible officer.
- 7.5 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. This instrument sets out these additional responsibilities for England only.
- 7.6 The Department of Health has held two public consultations on the regulations for the role of responsible officer (see paragraphs 8.1 and 8.2 below). The first consultation in 2008 received 126 responses and the second consultation in 2009 received 117 responses. Both public consultations helped inform the development of the responsible officer regulations including which organisations should be designated to nominate or appoint a responsible officer, and the duties and responsibilities of the officer.

³ Healthcare professional regulation: Public consultation on proposals for change, Department of Health, July – November 2006

http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_062974

⁴ Trust, Assurance, and Safety, Department of Health, 21 February 2007

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

⁵ The Health and Social Care Act 2008

http://www.opsi.gov.uk/acts/acts2008/pdf/ukpga_20080014_en.pdf

- 7.7 The regulations aim to provide the basis for consistent action by setting clear functions and responsibilities for responsible officers. By setting out how responsible officers cooperate with the General Medical Council they help to bridge the ‘regulatory gap’.
- 7.8 NHS Professionals Ltd (which falls within paragraph 20(a) of the Schedule) is a unique organisation. It was established as a Special Health Authority to be the NHS's own locum agency. As a special health authority it was not able to tender for inclusion on the NHS PASA framework agreement referred to in paragraph 20(b) of the Schedule to the regulations. However it is no longer a special health authority and so is not covered by paragraph 16 of the Schedule; it therefore needs to be listed separately.
- 7.9 The Independent Doctors Forum (paragraph 24 of the Schedule) represents doctors who work outside the usual structures but who provide healthcare directly to patients. It approached the Department to undertake the role of responsible officer for its members. It has been designated as it is considered by the Department to have appropriate arrangements in place for appraisal and clinical governance that support the role of a responsible officer.
- 7.10 Where surgical procedures for the purpose of religious observance , such as circumcision, are carried out or supervised by a medical practitioner the procedures are part of the practitioner’s medical practice. That practice is regulated by the General Medical Council and organisations that provide such services are designated in line with other organisations where the healthcare is provided by doctors (paragraph 26(1)(c)]of the Schedule). As the responsible officer role relates only to doctors, the designation excludes organisations that use only non-medical staff to carry out the procedures.
- 7.11 Some insurance policies such as holiday insurance provide medical services as part of the cover. The organisations that provide such services on behalf of the insurance company are providing healthcare, though the doctors they employ are a distinct category of healthcare provision. Such organisations have the same responsibilities to ensure they provide quality care and their doctors are supported in improving that care. Such organisations are covered by paragraph 38 of the Schedule to the regulations.
- 7.12 Employers have responsibilities for the appraisal and development for their staff. Primary care organisations and Deaneries have similar responsibilities in terms of doctors on their Performers Lists and postgraduate trainees respectively. Other organisations that are designated do not have those responsibilities and, usually, any costs are incurred by the individual doctor. Regulation 14(3) recognises these arrangements and provides for organisations to recover the costs related to the role of the responsible officer, for example for undertaking appraisals for those doctors who are not employees, postgraduate trainees or on a Performer List. For example membership organisations such as Faculties who are funded through the subscriptions of members will be able to recover the costs from those members that have a connection to under Regulation 10.

8. Consultation outcome

- 8.1 The first public consultation on the role of responsible officers was held between July 2008 and October 2008. There were 126 responses to this consultation and the Department's response document was published in May 2009⁶.
- 8.2 The second public consultation on the responsible officer draft regulations and guidance ran between August 2009 and October 2009. The consultation audience included Primary Care Trusts, independent healthcare providers, Royal Colleges, private companies in the pharmaceutical industry, and individual doctors. There were 117 responses to the consultation and the Department has made a number of changes based on the key issues raised:
- a locum doctor will have a prescribed connection to a designated body, and relate to a responsible officer, as there were concerns that this group of doctors was not supported by the regulations;
 - an appearance of bias will also be cause to nominate or appoint a second responsible officer (as well as a conflict of interest), as there were concerns that the provisions for addressing conflicts of interest were unduly biased in favour of the designated bodies; and
 - doctors in postgraduate training will relate to the responsible officer in their postgraduate medical deanery.

The Department's response to the consultation is available on the Department's website⁷.

9. Guidance

- 9.1 The Department has published 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 document is available on the Department's website⁷.

10. Impact

- 10.1 The impact on business, charities or voluntary bodies is limited to designated organisations employing or contracting with one or more licensed medical practitioners. Further details are set out in the impact assessment.
- 10.2 Following the implementation of this policy it is estimated that there will be around 975 responsible officers across England, Scotland and Wales. It is

⁶ Response to the consultation on responsible officers and their duties relating to the medical profession, Department of Health, May 2009
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851

⁷
<http://www.dh.gov.uk/en/Managingyourorganisation/Workforce/Professionalstandards/ProfessionalRegulationandPatientSafetyProgramme/TacklingConcernsLocally/ResponsibleOfficers/index.htm>

expected that these will be existing staff, such as Medical Directors, and many of their functions are those that should already be carried out in most organisations. The average annual cost is estimated to be £22m but it is worth noting that this estimate is of economic impact and includes (non-financial) opportunity costs.

- 10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the OPSI website.

11. Regulating small business

- 11.1 The legislation applies to small business.
- 11.2 The Impact Assessment details the provisions set out for small businesses in the section Cost of Appointing a Responsible Officer on Small Firms on page 22. The instrument allows for a doctor to be nominated or appointed as the responsible officer for more than one designated body. This enables small organisations to share one responsible officer and incur costs that are proportionate to their responsibilities.

12. Monitoring & review

- 12.1 The instrument aims to improve local systems of assuring good medical practice and to bridge the regulatory gap between local healthcare organisations and the General Medical Council.
- 12.2 A measurable outcome will be a reduction in the number of referrals to the General Medical Council where issues of concern of doctors' fitness to practice are identified earlier and handled at a local level. Currently about one third of all referrals are not fitness to practise issues and are returned to employers for local action with no further national action. A closer relationship between the national regulator and employers should reduce these cases and improve the efficiency with which they are managed.
- 12.3 This policy and this instrument will be reviewed as part of the review of the implementation programme of the White Paper *Trust Assurance and Safety* currently planned for 2011.

13. Contact

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