EXPLANATORY MEMORANDUM

THE GENERAL MEDICAL COUNCIL (LICENCE TO PRACTISE AND REVALIDATION) REGULATIONS ORDER OF COUNCIL 2012

2012 No. 2685

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 Order approves the General Medical Council (Licence to Practice and Revalidation) Regulations 2012 ("the Regulations"), and revokes the General Medical Council (Licence to Practise) Regulations Order of Council 2009 (S.I. 2009/2739)[1]. The Regulations are made by the General Medical Council ("the GMC") in relation to the licensing and revalidation of medical practitioners. The Regulations come into force on the 3rd December 2012.

2.2 This Order is made under powers inserted into the Medical Act 1983 ("the 1983 Act") by the Medical Act 1983 (Amendment) Order 2002 (S.I. 2002/3135), which itself was made under powers in section 60 of the Health Act 1999.[2] Where not yet in force, the relevant powers will be commenced to come into force on the same date as the Order.

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

None

4. Legislative Context

4. The GMC is the independent regulator for doctors in the UK. Its main statutory objective is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. It has power to make the Regulations, which relate to the GMC's legislative basis and procedures for issuing a license to practise and the revalidation of such licences. While retaining licence to practise provisions from the 2009 Regulations (with modifications), the main purpose of the regulations is to include a requirement for the revalidation of medical practitioners, which will usually be carried out at five yearly intervals. Revalidation is an evaluation of a medical practitioner's fitness to practise in order for that practitioner to continue to hold a licence to practise.

[1] http://www.legislation.gov.uk/uksi/2009/2739/pdfs/uksi_20092739_en.pdf

[2] The powers have since been subject to certain amendments by S.I. 2006/1914, S.I. 2008/3131 and S.I 2010/234.

4.2 Before revalidation can begin, the necessary primary legislation must be in force. Amendments to the Medical Act 1983 (the Act) have already been made but have not yet been commenced. Once they are in force, the Act will provide the broad framework and context in which the Regulations will operate.

4.3 The Regulations will also operate in conjunction with the Medical Profession (Responsible Officer) Regulations 2012[3] and the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010[4]. Their operation will also be accompanied by guidance prepared by the GMC.

5. Territorial Extent and Application

This instrument applies to the United Kingdom.

6. European Convention on Human Rights

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

7 Policy background

7.1 Contrary to public belief, there is no proactive regulatory policy to assess a doctor's fitness to practise, following qualification. The existing system is reactive only when concerns are raised about doctors. Intervention is necessary to bridge this gap by strengthening existing regulatory mechanisms. The purpose of revalidation is to mandate a periodic assessment of every doctor to provide assurance to the public, employers and other healthcare professionals that he or she remains fit to practise medicine.

7.2 Plans for the revalidation of doctors in the UK have been under discussion for more than a quarter of a century. The GMC initially committed to introduce revalidation in 1999-2000 in the immediate aftermath of the hearings of allegations of serious professional misconduct against three doctors at the Bristol Royal Infirmary. Link:
http://www.bristol-inquiry.org.uk/final_report/index.htm

7.3 In December 2004, the fifth report from the inquiry into the murders of hundreds of patients by Dr Harold Shipman concluded that the plans outlined by the GMC for revalidation as proposed, were not sufficiently robust to protect patients. It recommended a complete review of both appraisal and revalidation so that revalidation would provide more effective safeguards for patients. Link:
http://www.shipman-inquiry.org.uk/fifthreport.asp

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[3] S.I. 2010/2841, which was amended by S.I. 2011/2581 and S.I. 2012/476.

[4] S.R.(N.I.) 2010 No. 222.

7.4 Consequently, in July 2006, the Department of Health published a review of professional regulation by the Chief Medical Officer (CMO) for England, *Good doctors, safer patients*.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232
Following consultation on the document the response was published in February 2007 in the Department of Health document, *Trust, Assurance and Safety - the Regulation of Health Professionals in the 21st Century*. Links follow:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

7.5 On the 16th November 2009 in preparation for the introduction of medical revalidation, the GMC changed the registration arrangements for doctors practising medicine in the UK. From that date, a doctor must hold both registration and a licence to practise with the GMC to allow them to practise medicine. The change in UK law meant that the activities that were restricted to registered doctors prior to 16 November 2009 could only then be undertaken by doctors holding registration with a licence to practise. At the present time the licence to practise is open ended but once revalidation commences it will have to be renewed via the revalidation process at least once every five years.

7.6 A significant further step in preparations for medical revalidation occurred on the 1 January 2011 when the Medical Profession (Responsible Officer) Regulations 2012 came into force. Responsible Officers are locally-based senior doctors with specific responsibility for overseeing the performance and conduct of doctors working for healthcare organisations.

http://www.legislation.gov.uk/uksi/2010/2841/pdfs/uksi_20102841_en.pdf

7.7 Responsible officers have a statutory role in preparing systems and processes within their organisations for the implementation of medical revalidation. They will play a key role in supporting doctors to improve the quality of care they provide and in ensuring that prompt action is taken to protect patients where concerns arise about the practice of individual doctors.

7.8 Following the consultation the GMC undertook on the General Medical Council (Licence to Practice and Revalidation) Regulations 2012, a change was made to the regulations to allow for a small number of doctors who do not have a prescribed connection to a designated body, under the responsible officer regulations, to have recommendations made by a 'suitable person'. All suitable persons must be fully registered and licensed doctors and either be an existing responsible officer, or hold a post in an organisation with accountabilities and responsibilities similar to those of a responsible officer. The GMC must approve anyone acting as a suitable person.

7.9 On February 8th 2011 the House of Commons Health Committee published 'Revalidation of Doctors': Fourth Report of Session 2010-11. In the report, they called for no further delay to the implementation of medical revalidation. Link:

http://www.publications.parliament.uk/pa/cm201011/cmselect/cmhealth/557/55702.htm

7.10 The Government response was published in March 2011 and outlined three tests of readiness Ministers required to be met prior to medical revalidation commencing:

• design readiness: medical revalidation is right for doctors and for patients and has been properly streamlined and made proportionate;

• organisational readiness: the health sector has the systems in place to be able to move to implementation (responsible officers, appraisal, clinical governance, etc.);

• business case readiness (testing the components of revalidation): so that we have clear evidence of the benefits that revalidation will deliver and that it can be implemented in a way that is cost effective and affordable.

Link: http://www.official-documents.gov.uk/document/cm80/8028/8028.pdf

7.11 In February 2011, the Department of Health published a command paper *Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers*. This paper set out proposals for the regulatory system for healthcare workers across the UK and social workers in England. Chapter five, Ensuring Continuing Fitness to Practise confirmed the commitment to supporting the GMC to implement a proportionate and effective system of medical revalidation. The command paper can be found at the following link: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_124374.pdf

7.12 As a result of piloting and consultation, the proposed model of revalidation is more streamlined than the original blueprint conceived five years ago and builds primarily on existing systems of annual appraisal and clinical governance that should already be in place locally.

7.13 The core framework for medical revalidation is based on the GMC's Good Medical Practice guidance for doctors. Good Medical Practice (GMP) sets out the principles and values on which good practice is founded; these principles together describe medical professionalism in action.

7.14 Doctors will be expected to participate in an annual appraisal that is based upon the principals of GMP. They will need to maintain a portfolio of supporting information to bring to their appraisals as a basis for discussion with their appraiser. Over the revalidation cycle, this portfolio will span several years (usually five) and must cover work for every employer and contracting organisation with which the doctor has worked. Their responsible officer will then make a judgement about whether or not they should recommend to the GMC that the doctor is revalidated. For doctors in particular specialties, the appraiser or responsible officer may draw on high-level guidance from the relevant Royal College to support the appraisal and recommendation process.

7.15 During each five-year revalidation cycle, the body of supporting information doctors bring to appraisal must show evidence of:

- continuing professional development;

- quality improvement activity;
- significant events;
- feedback from colleagues;
- feedback from patients; and
- review of complaints and compliments.

7.16 If during the revalidation process concerns about a doctor's fitness to practise come to light, the GMC can instigate fitness to practise proceedings.

7.17 Following revalidation of a doctor, the GMC will confirm that the doctor may continue to hold a licence to practise unless the licence has been withdrawn as a result of: non-co-operation with the revalidation process; fitness to practise proceedings; or for other reasons.

7.18 This model will ensure that existing high levels of public trust and confidence in the medical profession are maintained and demonstrate to the public that all licensed doctors are up to date and fit to practise.

Details of the proposed Order

7.19 The Order approves the Regulations made by the General Medical Council on 27th September 2012 under powers in Part IIIA of the Medical Act 1983 ("the Act") in relation to licence to practise and revalidation of medical practitioners.

Regulation 2 makes provision for the giving of notices.

Regulation 3 makes provision so that a medical practitioner will automatically be granted a licence on registration under the Act. Provision is made for the grant of a licence to a practitioner in certain other specified circumstances. Provision is also made for a doctor holding registration without a licence to apply for one, subject to certain requirements set out in the regulation.

Regulation 4 provides for the withdrawal of a licence where a medical practitioner so requests, where the Registrar is satisfied that it was fraudulently or otherwise incorrectly obtained, or where the Registrar decides to withdraw the practitioner's licence following a failure to comply with the revalidation process provided for in regulation 6. It also provides for withdrawal of a licence in cases where the practitioner's registration comes to an end other than upon a determination by a Fitness to Practise Panel or an Interim Orders Panel. It sets out procedural requirements which apply in certain cases before the licence can be withdrawn.

Regulation 5 provides for the restoration of a licence after withdrawal under regulation 4, setting out the procedure that applies. Under regulation 5(5) and (6), the Registrar may require the practitioner to undergo revalidation prior to reaching a decision on the application for restoration of a licence, where the practitioner has not undergone revalidation for at least 5 years previously, or

where the Registrar has reasonable grounds for believing that the practitioner requested the withdrawal of their licence in order to avoid revalidation.

Regulation 6 provides for the revalidation of a practitioner. Paragraphs (1) to (3) provide for a notice of a submission date for the purposes of the revalidation of a practitioner to be served on a practitioner (other than certain excepted practitioners) once in every five year period unless the Registrar sees fit to serve a notice on another occasion. Under paragraphs (4) and (5), the practitioner must, by the submission date, provide evidence or information to the Registrar relating to revalidation required by statutory guidance and take reasonable steps to arrange for the practitioner's responsible officer (if any) to prepare a statement on whether a recommendation as to the practitioner's fitness to practise can be made. Where the practitioner has no responsible officer, paragraphs (6) and (7) allow the practitioner to arrange for a suitable person to prepare a statement. A suitable person must be a registered medical practitioner who is approved by the Registrar as suitable to prepare a statement and is either a responsible officer in respect of another person, who does not have a formal statutory connection with the practitioner in question, or a person who holds a post which the Registrar is satisfied includes similar responsibilities to that of a responsible officer. Under paragraph (8), where the practitioner has no responsible officer and no suitable person, the Registrar may request the completion of an assessment at the practitioner's own cost. The Registrar has the power to require or request further evidence or information in accordance with the provisions set out in paragraphs (9) to (13) and power under paragraph (14) to charge a fee for evaluating certain information in support of revalidation.

Under paragraph (15), where the Registrar considers it reasonable to do so the Registrar may cancel a submission date or defer the practitioner's revalidation until such time as the Registrar considers reasonable. By virtue of paragraph (17), at any time after a cancellation or deferral under paragraph (15), the Registrar may give notice of a new submission date and seek further evidence or information from the practitioner. Under paragraph (18), save where the practitioner's licence is withdrawn, following the revalidation of a practitioner the Registrar must confirm by notice that the practitioner's licence may continue. Paragraph (19) allows for corrections.

Regulation 7 gives the Registrar power to refer to a Registration Panel any question arising in relation to the grant, withdrawal or restoration of a licence, or in relation to the revalidation of a practitioner, and requires the Registrar to take the Panel's advice into account in reaching any decision.

Regulation 8 provides for the restoration of a licence following the determination of a Fitness to Practise Panel that a practitioner's name should be restored to the register.

Regulation 9 revokes the General Medical Council (Licence to Practise) Regulations 2009.

8. Consultation Outcome

8.1 The Order itself has been subject to a twelve-week consultation by the GMC from 17 October 2011 to 27 January 2012. The Council received a paper at the 18

July 2012 meeting outlining the results of the consultation and the draft Regulations.
http://www.gmc-uk.org/4b___Licence_to_Practise_and_Revalidation_Regulations_2012.pdf_49446383.pdf
At the September 27 2012 meeting, the Council considered revisions to and sealed the (Licence to Practise and Revalidation) Regulations 2012.
http://www.gmc-uk.org/04b___Revalidation_Licence_to_Practise_and_Revalidation_Regulations.pdf_49967413.pdf
http://www.gmc-uk.org/about/council/13937.asp

9. Guidance

The Department of Health has not issued any guidance in relation to this Order.

The General Medical Council has published comprehensive guidance relating to:

- The Good Medical Practice framework for a doctors appraisal
- Supporting information required for appraisal
- Meeting the requirements for the first cycle of revalidations
- Developing and administering questionnaires
- Responsible Officer protocol for making recommendations to the GMC

http://www.gmc-uk.org/static/documents/content/GMC_Revalidation_A4_Guidance_GMP_Framework_04.pdf
http://www.gmc-uk.org/static/documents/content/Supporting_information_for_appraisal_and_revalidation.pdf
http://www.gmc-uk.org/static/documents/content/Developing_implementing_and_administering_questionnaires_.pdf
http://www.gmc-uk.org/static/documents/content/Meeting_our_requirements_in_the_first_cycle.pdf
http://www.gmc-uk.org/doctors/revalidation/13631.asp

10. Impact

10.1 The main costs of revalidation are borne by employers and relate to the time taken for doctors to undertake appraisal. An estimated 27% of doctors do not currently undergo appraisal and will be required to in order to meet the requirements of revalidation, incurring an estimated 'opportunity cost' of nine hours per year for the doctor and four hours per year in appraiser time. Further, relatively small, costs will be incurred, for example through the time required for Responsible Officers to undertake their role, collection of patient and colleague feedback, and costs to the regulator.

10.2 Revalidation is expected to result in significant benefits, most notably through increased public trust and confidence in doctors and improved patient safety, outcomes and quality of care.

10.3 A detailed analysis of the costs and benefits associated with medical revalidation will be published on the Department of Health website on 5 November 2012.

11. Regulating small business

11.1 The legislation applies to all doctors with a license to practise, so may incur some impact on small businesses. This impact is, however, expected to be small, as there are very few small firms providing health services who are the sole employers of private doctors. Most doctors working in the private sector also undertake NHS work. Where this is the case, the Responsible Officer regulations work in such a way that

even if a doctor has just one session a week in an NHS facility, their responsible officer is the one for the NHS facility. It is therefore likely that the NHS will incur a relatively higher proportion of the cost of the revalidation process.

11.2 One possible impact of note for small firms is the potential need to implement systems to enable the administration of appraisal and revalidation information. However, the revalidation process has been designed to enable a proportionate approach to managing information and, in its simplest form, could be administered as a paper-based exercise. The proposed medical appraisal process, in particular, was streamlined throughout its development and subsequent testing and piloting, by over 4,000 doctors, has shown it takes no longer for an appraisee and less time for an appraiser, to complete a medical appraisal, than the models currently used.

12 Monitoring and review

The policy will be monitored during the initial five year implementation phase by the Governance structures currently in place at the GMC (UK Revalidation Programme Board) and by the Revalidation Delivery Boards in England, Northern Ireland, Scotland and Wales and any successor governance structures.

13. Contact

Department of Health Tel: 0113 254 6001 or email: Dave.M.Smith@dh.gsi.gov.uk can answer any queries regarding the instrument.