EXPLANATORY MEMORANDUM TO

THE MEDICAL ACT 1983 (AMENDMENT) AND MISCELLANEOUS AMENDMENTS ORDER 2006

2006 No. 1914

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

2. Description

2.1 The Order amends the Medical Act 1983. Unrelated minor amendments are also made to the Opticians Act 1989 and the Nursing and Midwifery Order 2001. The Medical Act 1983 provides for the regulation of medical practitioners by the General Medical Council (GMC): the Opticians Act 1989 provides for the regulation of opticians by the General Optical Council; the Nursing and Midwifery Order 2001 provides for the regulation of nurses and midwives by the Nursing and Midwifery Council. The amendments deal, amongst other things, with new registration arrangements for medical practitioners qualifying outside the European Economic Area (including the abolition of the register of practitioners with limited registration), new training and supervision requirements for recently qualified medical practitioners, further developments in respect of the GMC's fitness to practise procedures, and unrelated amendments to the Opticians Act and the Nursing and Midwifery Order.

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

3.1 None

4. Legislative Background

4.1 This Order in Council is made under the powers given to her Majesty under sections 60 and 62(4) of the Health Act 1999. Section 62(9) requires that the Order be laid before, and approved by resolution of both Houses of Parliament before any recommendation is made to Her Majesty to make the Order. Under paragraph 9 of Schedule 3 to the Health Act 1999, the Secretary of State is required to publish a draft of the Order at least 3 months before the Order (which may be modified as she sees fit) is laid in draft before both Houses of Parliament. The Secretary of State must lay the Order with a report about consultation that she is required to carry out. The draft Order was published on 2 November 2005 and the period of consultation ended on 30 January 2006.

The purpose of the Order is to give effect to Government policies described in section 7.

5. Extent

5.1 This instrument applies to England and Wales, Scotland and Northern Ireland.

6. European Convention on Human Rights

6.1. The Minister of State for Delivery and Quality at the Department of Health, Andy Burnham MP has made the following statement regarding Human Rights:

"In my view the provisions of the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006 are compatible with the Convention rights."

7. Policy background

Policy;

- 7.1 Extensive reforms of the Medical Act 1983 were introduced by the Medical Act 1983 (Amendment) Orders in 2000 and 2002. This Order continues the reform of the regulation of medical practitioners by the General Medical Council in line with the Government's policy to modernise the regulation of all health and social care professionals
- 7.2. The major reforms proposed in this Order are:
- New registration arrangements for practitioners qualifying outside the European Economic Area, including the abolition of limited registration.
- 7.2.1 The Order proposes to abolish the register of practitioners with limited registration. Those practitioners who are suitably qualified will be granted full registration immediately irrespective of where in the world they obtained their primary medical qualification. It is also proposed to end the arrangement whereby those wishing to be granted limited registration needed to have the offer of a job before they could be registered. This had the effect of discriminating against international medical graduates in particular. To ensure an appropriate measure of public protection, newly registered practitioners and, in some cases, those newly restored to the register will be required to work in an approved practice setting until their first revalidation to ensure that they receive the support necessary to ensure patient safety. The Order also proposes special arrangements for dealing with the temporary registration of certain visiting eminent specialists.
- New training and supervision requirements for recently qualified practitioners
- 7.2.2 Since 2002, the GMC's Education Committee has undertaken a major review of, and public consultation on, general clinical training (the training of provisionally registered doctors).
- 7.2.3. The changes proposed in the draft Order are designed to provide a responsive, accountable, transparent, proportionate, clear and robust process to ensure that outcomes are delivered effectively in training programmes. The objective is to enable the Education Committee to respond more quickly when strategic change is required by

proposing that many of the requirements currently in primary and secondary legislation be put into determinations made by the GMC's Education Committee.

- 7.2.4. The proposed insertion of a new section 10A (Programmes for provisionally registered doctors) would allow the Education Committee to issue determinations on:
 - o the training to be undertaken by those participating in programmes for provisionally registered doctors (PPRD) prior to the grant of full registration;
 - o which bodies may deliver programmes and the bodies by whom a PPRD participant is to be employed;
 - o the content and standards of programmes;
 - o the activities which may be undertaken by provisionally registered doctors;
 - o the arrangements for certification; and
 - o special provisions to adapt programmes to address the issue of a person who has, or has had, a disability.
- Further developments in respect of new fitness to practise procedures and licensing arrangements, introduced in the Medical Act 1983 (Amendment) Order 2002
- 7.2.5. Some adjustments have been made to the fitness to practise arrangements introduced by the Medical Act 1983 (Amendment) Order 2002. The draft Order proposes that all doctors will need to satisfy the Registrar of the GMC at the point of entry to the register that their fitness to practise is not impaired a concept which embraces health, conduct, character, probity, knowledge and skills. The Order proposes for the first time that the GMC should have power to erase from the register a practitioner who is shown, subsequent to registration, to have failed to declare, at registration, an impaired fitness to practise. The draft Order also proposes to give the GMC powers to disclose additional information relating to a practitioner's fitness to practise in certain circumstances.
- 7.2.6. The draft Order also proposes arrangements for the consensual disposal of certain cases where the Investigation Committee is considering an allegation and the practitioner agrees to comply with such undertakings as the Committee considers appropriate. The draft Order also proposes that, to ensure that a practitioner who has been suspended from the register derives no unintended benefit from their situation, he or she should continue to be treated as if their name remained on the register to ensure that any possible fitness to practise action may be appropriately pursued.
- 7.2.7. The draft Order also includes proposals for mandatory professional indemnity/ insurance cover at the point of registration and throughout the practitioner's registration (or while they remain licensed to practise when those arrangements comes into force). Failure to maintain adequate and appropriate cover will be a fitness to practise issue.
- 7.2.8 In addition the draft Order seeks to clarify the GMC's power to require a registered practitioner to undertake revalidation of a licence to practise whenever they see fit.
- More streamlined decision making and procedures within the General Medical Council.

- 7.2.9. The draft Order proposes a number of measures to help streamline the decision making and procedures of the General Medical Council. In particular, it proposes that a number of functions previously exercised by the General Council should in future be carried out by the Registrar. It is felt that this is in line with other provisions within the Medical Act and avoids the necessity of the General Council having to become involved in the fine detail of every case. The Registrar will, in any case, be acting in accordance with the overall policy set by the General Council and will, where necessary, be able, and be expected, to take advice from the General Council or a Registration Panel as appropriate.
- 7.2.10. The draft Order also propose, for the sake of improved administrative efficiency, to break the automatic link between a medical practitioner's annual retention fee renewal date and the date of their first registration. The proposed amendment is designed to remove the need for practitioners whose names are being restored to the register shortly before payment of their annual retention fee would normally have fallen due (i.e. on the anniversary of their first registration) to have to pay two retention fees in quick succession. This was not only potentially unfair for practitioners but was also administratively inefficient for the GMC. The GMC are satisfied that this proposal will have no significant adverse effect on their income and is likely to result in only minor consequential amendments to their Fees Regulations.

Consultation;

7.2.11. Around 70 responses were received from organisations and individuals to the public consultation exercise that was conducted between 31 October 2005 and 30 January 2006. The large majority of responses were positive. There was widespread support for the abolition of the register of practitioners with limited registration and the proposal to introduce "approved practice settings". The proposals to introduce new temporary registration arrangements for visiting eminent specialists. There was also support for the proposals to streamline the GMC's administrative procedures and to clarify their powers to obtain and disclose information in fitness to practise cases. In addition, there was majority support for the proposal to introduce a mandatory professional indemnity/ insurance requirement for all registered doctors. Fuller details of the consultation exercise are contained in "The Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006: Report on consultation" on the Department of Health website at url:

http://www.dh.gov.uk/Consultations/ResponsesToConsultations/fs/en

Consolidation;

7.2.12. This is the latest of a series of section 60 Orders amending the Medical Act 1983 and the Department is conscious that the Act is now approaching the point where consolidating all the Act's provisions would be helpful. However, Ministers consider that it would be appropriate to assess the potentially significant impact of the recent Reviews of the revalidation of doctors and related matters, and of Non-Medical Regulation, before embarking on a consolidation exercise.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

9.1. Paul Atkinson, Project Manager, Professional Regulation Branch at the Department of Health; Tel: 0113 254 5311 or e-mail: paul.atkinson@dh.gsi.gov.uk can reply to any queries regarding the instrument.

Regulatory Impact Assessment – Medical Act 1983 (Amendment) & Miscellaneous Amendments Order 2006

1. Title of Proposal

The Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006.

2. Purpose and intended effect

• Objective

The Government's objective is to improve public safety and improve the care of patients by further modernisation of the regulation of medical practitioners and streamlining of the operation of the General Medical Council (GMC). In particular, this Order:-

- Abolishes the register of practitioners with limited registration and provides for practitioners who are considered by the GMC to be acceptably qualified to be granted full registration irrespective of where they qualified;
- o Makes changes to the training and supervision requirements for recently qualified medical practitioners;
- Further develops the GMC's fitness to practise procedures introduced in the Medical Act 1983(Amendment) Order 2002;
- Provides for more efficient decision making and procedures within the GMC;
 and
- o Makes certain other administrative changes which are being introduced for all healthcare regulators as they become the subject of a section 60 Order, e.g. mandatory professional indemnity/ insurance for practising registrants.

• Background

The Government and the General Medical Council are working together to modernise the regulation of medical practice in line with the wider reform of the regulation of healthcare professions. Using powers provided by section 60 of the Health Act 1999, the Department of Health and the GMC have worked collaboratively to carry forward the reform programme begun in the Medical Act 1983 (Amendment) Order 2000 and taken further in the Medical Act 1983 (Amendment) Order 2002.

The latest Order introduces additional improvements in a number of areas:-

• new registration arrangements for practitioners qualifying outside the European Economic Area (EEA), including the abolition of limited registration;

- new training and supervision requirements for recently qualified practitioners;
- further developments in respect of the new fitness to practise procedures and licensing arrangements introduced in the 2002 Order; and
- more streamlined decisions making and procedures.

• Rationale for government intervention

The Government is committed to updating the regulations of healthcare professionals and several high profile regulatory problems have indicated how important effective regulation is if the public is to be adequately protected. The strengthening of the regulation of doctors began with the Medical Act 1983 (Amendment) Order 2000 and continued with the Medical Act 1983 (Amendment) Order 2002. This Order continues the modernisation process and is independent, and outside the terms of reference, of the Chief Medical Officers Review arising from the publication of the Fifth Report of the Shipman Inquiry.

3. Consultation

• Within government

Department of Health has regularly consulted colleagues in the Welsh Assembly, Scottish Executive, and Department of Health, Social Services and Public Safety Northern Ireland with regard to the draft Order. We have also cooperated with the Home Office in connection with procedures for international medical graduates and immigration rules. The Department for Constitutional Affairs was contacted as part of the public consultation and indicated that they were content with the proposed arrangements for dealing with Legal Assessors in article 53 of consultation draft of the Order.

• Public consultation

The GMC carried out a public consultation on proposals for a new system of registration and licensure, which included a raft of measures it was hoping to see introduced into the next section 60 Medical Act Order between 7 July 2003 and 10 October 2003. Consultation proposals were sent to 325 organisations in the UK and abroad, 1000 registered medical practitioners, 35 Council members and 134 other individuals who had expressed an interest in the subject. Responses were received from 59 organisations and 118 individuals (most of them doctors), a total of 177 responses to the GMC consultation.

A full statutory consultation on the draft Order was held between the beginning of November 2005 and the end of January 2006. A report has been prepared on the outcome of the public consultation and the draft Order has been amended in the light of responses to the consultation.

4. Options

- (i). Do nothing. Given that the Government has already introduced considerable improvements to the regulation of medical practitioners it would not make sense for that process to be stalled part way through the process. Were one or more patient or public protection issues to arise as a result of a decision not to proceed at this stage there would be understandable criticism of the Government as a result.
- (ii) Await the outcome of the Chief Medical Officer's Review before publishing the draft Order for consultation. The process of reform encompassed in this Order started before the announcement of the CMO's review and is essentially a tidying up of the legislation related to the GMC. The contents of this Order will be valid whatever recommendations the Chief Medical Officer makes and for the reason set out at (i) above it is not considered expedient to delay the public consultation on the Order until after the CMO has reported on the outcome of his review.
- (iii) To proceed with Parliamentary consideration of the draft Order with a view to introducing its provisions progressively from December 2006.

5. Costs and Benefits

Sectors and groups affected

The General Medical Council and medical practitioners are likely to be the groups most affected by the measures set out in the draft Order. The abolition of limited registration will be of particular interest to international medical graduates from outside the EEA who may now apply for full registration immediately without having first to apply for limited registration. Another benefit of the removal of the register of practitioners with limited registration is the removal of the requirement to have the offer of a job before a practitioner's name may be entered on the register. This removes an obstacle which was a particular barrier to non-EEA international medical graduates. Even when they had passed the GMC's PLAB test[s] they often had to wait many months for registration because they could not be offered a job until they had been registered and they could not be registered until they had been offered a job or sponsorship, typically from a medical Royal College.

It is believed that there will be a positive affect for patients and the public as a result of the greater openness with regard to the disclosure of fitness to practise issues in the public interest.

Benefits

There are obvious benefits in terms of equity of treatment arising from the abolition of the register of practitioners with limited registration and its replacement with a system of full registration for practitioners who are able to satisfy the GMC that they are acceptably qualified irrespective of where in the world they obtained their qualification. The concept of an approved working environment (now referred to in the Order as an "approved practice setting") will ensure that newly registered medical practitioners and those newly restored to the register will receive an appropriate level of support in that significant stage in their career.

The streamlining of the administrative procedures is in line with the Government's objective for more efficient and transparent regulatory arrangements for healthcare professionals and should benefit both the public, health services and the medical profession. The clarification of the situation with regard to the GMC's disclosure of fitness to practise information is also helpful both for the regulator and the public.

Costs

It is not envisaged that there will be any significant cost implications for any of the proposals included in the draft Order. Some of them might even lead to savings. In 2003, for instance, the GMC calculated that the abolition of limited registration, which accounted at that time for about £4 million of the registration budget, would lead to a saving of £2 million per year in costs arising from dealing, for instance, with applications for renewal of limited registration or applications to move from limited to full registration. Even the requirement for mandatory professional insurance/indemnity cover for practising doctors should not make a significant difference to costs as almost all doctors already comply with the good practice, set out in *Good Medical Practice*, of having such cover.

Depending on the system of monitoring compliance with the requirement for mandatory indemnity/ insurance cover at the point of registration and retention on the register adopted, there may be additional administrative costs to be borne by the GMC which might be addressed by an adjustment of the registration/ retention fees for practitioners. Even if there were such an additional cost, it is considered justified by the increased assurance provided to patients that if they are subject to deficient practice and are awarded compensation then the mechanism to deliver the specified settlement is in place.

6. Small Firms Impact Test

It is not anticipated that there will be any significant impact on small firms in respect of this Order.

7. Competition Assessment

It is not anticipated that the measures proposed will have any impact on the market for the provision of medical services.

8. Enforcement, sanctions and monitoring

The General Medical Council, like other professional regulators, sets out standards for registrants. The General Council is ultimately responsible for the enforcement of these rules and regulations.

The rules and regulations made under the proposed Order will be subject to consultation before being submitted to the UK health departments for consideration by Parliament, using the negative resolution procedure and approval by the Privy Council.

The Council for Healthcare Regulatory Excellence, set up under the NHS Reform and Health Care Professions Act 2002, has a remit to report annually to Parliament on the effectiveness of professional regulation and to raise any matters it considers necessary with the Secretary of State and, where necessary, the devolved administrations.

9. Declaration and Publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: Andrew Burnham

Dated: 7th June 2006

Minister of State, Department of Health.

10. Contact for further information

Paul Atkinson Department of Health Tel 0113 254 5311

Email: paul.atkinson@dh.gsi.gov.uk