EXPLANATORY MEMORANDUM TO

THE HEALTH CARE AND ASSOCIATED PROFESSIONS (MISCELLANEOUS AMENDMENTS) ORDER 2008

2008 No.

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

2. **Description**

2.1 This Order makes a number of amendments to the

- Medical Act 1983
- Opticians Act 1989
- Osteopaths Act 1993
- Chiropractors Act 1994.

2.2 These Acts make provision for the statutory regulation of doctors, opticians, osteopaths and chiropractors. Many of the amendments to these Acts relate to the governance arrangements of the General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC) and the General Chiropractic Council (GCC). The most significant change is that membership of these Regulators will cease to be partly elected and will become fully appointed. This Order also makes a number of other miscellaneous and consequential amendments. These other changes include provision enabling the GMC to maintain a list of people whom the GMC will register temporarily as doctors during certain types of major emergency.

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

3.1 Paragraph 10 of Schedule 1 to the Order inserts a new section 18A into the Medical Act 1983 which will, for the first time, allow both for group registration by the GMC of individuals as doctors and for the registration by them of individuals who do not possess the qualifications normally required for registration. An explanation of these provisions is given below in paragraphs 7.3 to 7.8.

4. **Legislative Background**

4.1 The GMC, GOC, GOsC and GCC are statutory bodies governed by provisions set out in the Medical Act 1983, the Opticians Act 1989, the Osteopaths Act 1993 and the Chiropractors Act 1994 respectively. Each of these Regulators maintains a register of those who are fit and proper people to practise in the professions for which they are responsible. They set the standards which people have to meet if they are to be entered onto their registers and run the disciplinary procedures for registrants who are alleged to have fallen short of the standards expected of them.

4.2 The Acts mentioned above make provision for the constitutions of these four Regulators. In all cases, the membership of the Councils is made up of a number of lay members appointed by the Privy Council, and a number of professional members who are either elected representatives of those registered with the relevant Council or have been appointed to the Council because of their background in the education or training of members of the relevant profession. The GOC also, at the moment, has four doctors as members of its Council. The Acts also set out the constitutional arrangements for the statutory committees of each Council. Some of the detail relating to Council and committee structures of the Regulators is also set out in subordinate legislation. The Acts also

contain other provisions dealing with other governance issues such as the production of annual reports and accounts.

4.3 The White Paper "*Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century"* ("the White Paper") set out a programme of substantial reform to the system for the regulation of health care professionals. This was based on the results of consultation on two reviews of professional regulation published in July 2006: *Good doctors, safer patients* by the Chief Medical Officer for England, and *The regulation of the non-medical health care professions* by the Department of Health. The Order concentrates on implementation of the proposals set out in Chapter one of the White Paper, entitled, *Assuring independence: the governance and accountability of the professional regulators.*

4.4 Orders in Council under section 60 of the Health Act 1999 can be used to regulate health care professions, and in particular those that are currently regulated by the GMC, GOC, GOsC, GCC, the Nursing and Midwifery Council, the General Dental Council, the Health Professions Council and the Royal Pharmaceutical Society of Great Britain. This Order will be the second of three Orders in Council that will take forward the first set of White Paper changes to the governance arrangements of these regulators, although fewer changes are likely to be made in respect of the Royal Pharmaceutical Society of Great Britain, because of the anticipated establishment of the General Pharmaceutical Council to take over its regulatory functions.

4.5 The opportunity has also been taken to make a number of other changes to the various Acts to take account of developments elsewhere – in particular, of the passing of the Safeguarding Vulnerable Groups Act 2006 and the equivalent legislation in Scotland and Northern Ireland, and of emergency planning for dealing with emergencies such as an outbreak of pandemic influenza. The Order also contains some technical amendments and some consequential revocations of subordinate legislation.

5. Territorial Extent and Application

5.1 The Order extends to the United Kingdom.

6. European Convention on Human Rights

6.1 The Minister of State for Health Services, Ben Bradshaw, has made the following statement regarding Human Rights:

"In my view, the provisions of the Health Care and Associated Professions (Miscellaneous Amendments) Order 2008 are compatible with the Convention rights."

7. Policy Background

7.1 This Order makes a number of governance changes are to meet the following policy objectives:

- Extension and harmonisation of the health care professions' Regulators' duties of co-operation. The White Paper highlighted the need to ensure closer co-operation and co-ordination between Regulators and employers, and the need for regulators to consider the interests of stakeholders. Accordingly the GMC is given revised duties of co-operation, and the GOC, GOsC and GCC are given new duties of co-operation, with other bodies and individuals. This is in line with the revised duties of co-operation for the NMC included in the Nursing and Midwifery (Amendment) Order 2008.

- Reconstitution of the GMC, GOC, GOsC and GCC as fully appointed bodies. They are to be reconstituted as provided for by Order of the Privy Council ("the constitution Orders"). The constitution Orders will provide for fully appointed councils, rather than a mix of elected

professional members and appointed lay and other members, as at present (see again paragraph 4.2). All Councils will have parity of membership between lay and professional members to ensure that purely professional concerns are not thought to dominate their work – although the numbers of each will be in the constitution Order (for the time being, there will be statutory restrictions preventing lay majorities on the Councils, although some of the Regulators have indicated that they are considering a move to a lay majority when the provisions of the Health and Social Care Bill currently before Parliament allow for this to be legislated for in future section 60 Orders). Regulators must be seen to be independent and impartial in their actions. Doubts based on a perceived partiality have threatened to undermine patient, public and professional trust in the Regulators more generally. The composition of the Regulators is central to these perceptions. The Regulators may be seen as partial to their professionals because the professionals form the majority on the councils, or may be seen to be partial because their councils are thought to be elected to represent the particular interests of health professionals. Hence the moves to parity of membership and having independently appointed councils rather than professional members being elected by the profession.

- Revision of the constitutional arrangements for the statutory committees of the Regulators. Particularly as regards the GOsC and the GCC, the requirements in the framework Acts will be less prescriptive, and more generally, there will be more flexibility as regards the processes for appointing committee members. These essentially technical changes are intended to give the Regulators greater independence in managing how they deliver their statutory functions, within the overall framework set by the relevant Acts.

- Revision of the annual reporting requirements so that for the first time they are required to include a description of the arrangements that the Regulators have in place to ensure that they adhere to good practice in relation to equality and diversity, and a strategic plan. The Councils' reports and plans are laid before Parliament and so for the first time they will be required to inform Parliament about their future direction. Alongside the move, more generally, to greater independence of the Regulators from Government, it is important to strengthen the accountability of the Regulators to Parliament. This will ensure that there will continue to be checks and balances on the Regulators' exercise of their functions.

7.2 The other main changes will meet the following policy objectives:

- Changing the system for the approval of providers of primary UK medical qualifications. Instead of the list of approved providers being set out in the Act, the providers will be set out in an administrative list maintained and published by the GMC. The former restriction on only being able to add universities or combinations of universities to the list of approved providers has been removed, so now other bodies or combinations of bodies, for example university colleges and medical schools, can feature on the list in their own right. Previously, the Privy Council had a role both in adding providers to the statutory list (by Orders in Council) and in removing them (by a scheme of declarations), but this is all now left to the GMC itself. These changes are in line with the wider policy objective of giving the Regulators greater independence in managing and delivering their statutory functions.

- Giving new powers to the GOsC and GCC to make rules relating to the registration of osteopaths or chiropractors with qualifications gained before their registers were established and which are no longer recognised. These are to address specific difficulties faced by individuals who for a variety of reasons were unable to register during the transition period following the opening of the GOsC and GCC registers. In the main, they will be osteopaths or chiropractors who have been practising overseas, as the new arrangements will not be available to anyone who has practised as an osteopath or chiropractor in the United Kingdom since the end of the relevant transitional periods. All practitioners seeking to benefit from these arrangements will have to demonstrate that they are capable of the competent and safe practice of their profession, in order to ensure that professional standards are maintained.

- Enabling inclusion of a person in a barred list kept by the Independent Barring Board, or the adults' or children's lists kept by the Scottish Ministers, to be considered a reason for finding a registrant's fitness to practise is impaired or for turning down an application for registration. This is for the protection of vulnerable patients.

7.3 In addition, the Order also contains provisions enabling the GMC to keep an emergency powers doctors list. This will be a list of individuals who are called upon to act as doctors in the event of certain types of emergency having occurred, being in progress or being about to occur. The emergencies under consideration are those threatening serious damage to human welfare that involves or may cause loss of human life or human illness or injury.

7.4 These powers are, in essence, reserve powers. They are part of a strategy to put in place legislative arrangements now for dealing with an influenza pandemic or a similar national emergency, for example the emergence of a new virulent strain of viral haemorrhagic fever, so that as little reliance as possible would need to be placed on legislating once a pandemic had been declared.

7.5 However, it is, in practice, impossible to forecast the precise characteristics, speed or impact of all the highly infectious or deadly illnesses that could conceivably affect the United Kingdom. The Department's view is that, in the circumstances, the prudent thing to do is to provide for maximum, albeit reasonable, flexibility in the range of responses that might be made, and then if this type of emergency did arise, it would be for the Government and the GMC to co-operate together in providing a proportionate response that met the particular threat in question.

7.6 This strategy means that the powers are, on their face, very broad, although in practice the group that is most likely to be called upon, if the emergency is sufficiently dire, is recently retired doctors. Registration of this group might, for example, be a valuable tool in giving a wider range of suitably experienced people short-term prescribing rights for perhaps a limited range of prescription-only medicines. Consideration is being given to preparing this group, as they leave the register, by establishing their readiness to return in an emergency situation.

7.7 If the emergency strikes particularly quickly, and has a particular severe impact on a particular location, it may not be possible to identify each and every individual at the outset who needs to act as fully registered doctors – for example, final year medical students, who will not at that stage in their careers necessarily be known to the GMC, notwithstanding the links that the GMC has with universities that are intended to facilitate future registration. There are therefore arrangements for registration of an identified group of individuals as well as identified individuals, and for registration of individuals who do not possess all the qualifications normally required for registration.

7.8 It is emphasised that the existence of these powers is a purely precautionary measure. They do not reflect any change of risk level perceived by the Government. If the powers to register under section 18A were ever used, it is likely that the powers to impose conditions on the registration in section 18A(3) would also be used so as to limit the emergency powers doctors to a specific range of functions. Registration would only be temporary and the registrants would not acquire rights to practise as doctors elsewhere in the European Economic Area or retain their rights to practise in the UK once the emergency was over.

7.9 Mention is made of the recent consultation exercises on the wider package of measures relating to responding to pandemic influenza in paragraph 7.11.

Consultation

7.10 The Health Care and Associated Professions (Miscellaneous Amendments) Order was published in draft for public consultation on 22 November 2007. Consultation closed on 22 February 2008. 67 responses were received, showing overall support for the amendments set out in the draft Order. A report on the consultation has been laid before Parliament and is attached to this Memorandum.

7.11 The Department consulted more widely on its proposals for responding to an influenza pandemic as part of a separate consultation exercise, *Pandemic flu: a national framework for responding to pandemic influenza*, which closed on 22nd February 2008. That consultation document described the Government's strategic approach for responding to an influenza pandemic published jointly by the Department of Health and the Cabinet Office. It provided background information and guidance to public and private organisations developing response plans. It updated and expanded upon health advice and information contained in previous plans issued by UK health departments and was intended to replace those documents. There was also a public consultation exercise by the Department on possible changes to medicines and associated legislation for use during a pandemic, which closed on the same day.

Consolidation

7.12 There are no plans to consolidate the legislation amended by these Regulations.

8. Impact

8.1 An Impact Assessment is attached to this Memorandum.

9. Contact

9.1 Stuart Griffiths at the Department of Health, tel: 0113 254 5249 or e-mail Stuart.Griffiths@dh.gsi.gov.uk

HEALTH CARE AND ASSOCIATED PROFESSIONS (MISCELLANEOUS AMENDMENTS) ORDER

2008

Consultation Report

Executive Summary

1. The draft Health Care and Associated Professions (Miscellaneous Amendments) Order 2008 makes a number of amendments to the Medical Act 1983, Opticians Act 1989, Osteopaths Act 1993 and the Chiropractors Act 1994. These include:

   - New or revised duties of co-operation and new or revised duties to consider the interests of stakeholders

   - Improved arrangements for accountability to Parliament

   - Powers enabling the General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), and the General Chiropractic Council (GCC) to consider a persons fitness to practise as being impaired if that person has been included in a barred list kept by the Independent Barring Board or the children's or adults' lists kept by the Scottish Ministers

   - New constitutional arrangements for the GMC, GOC, GOsC and GCC (including a move to a fully appointed council and removal of the requirement for council members to be on certain committees)

   - New arrangements for the constitutions of statutory committees

   - Registration of Council members private interests, where this was not previously provided for

   - New provisions allowing for emergency registration in relation to emergencies involving or potentially involving large scale loss of human life or human illness (GMC only)

   - Replacement of the duty to name approved providers of medical qualifications in the Medical Act 1983 with a duty to publish a list of approved providers (GMC only)

   - Arrangements for the registration of Osteopaths and Chiropractors with older UK qualifications who were unable to register at the time the register was first opened under the transitional arrangements then in place (GOsc and GCC)

2. The draft Health Care and Associated Professions (Miscellaneous Amendments) Order 2008 was published for public consultation on 22 November 2007. Consultation closed on 28 February 2008. A summary of the responses is at Annex A.

Introduction

This paper sets out the outcome of the consultation on the draft Health Care and Associated Professions (Miscellaneous Amendments) Order 2008, which was published for consultation on 22 November 2007.

Background

The White Paper *Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century* ("the White Paper") set out a substantial programme of reform to the United Kingdom's system for the regulation of health care professionals based on the reviews *Good doctors, safer patients* and *The Regulation of the non-medical health care professions* which were published in 2006.

The draft Order sets out a range of amendments to take forward reforms identified in Chapter one of the White Paper, which concentrated on the governance and accountability of the professional regulators. It also included measures that are required to deliver other legislative requirements and some items identified by the regulators as needing urgent reform.

The Order contained measures that would affect professions regulated by

- General Medical Council
- General Optical council
- General Chiropractic Council
- General Osteopathic council
- Nursing and Midwifery Council.

The measures included in the draft order are intended to ensure a consistency of approach across all the regulators, and the consultation on the draft Order reflected this – seeking views on the amendments as they applied to all regulators rather than in respect of each regulator.

There were 67 responses to the consultation. Annex A sets out the consultation questions and provides a summary of the responses.

As a result of representations received from the Nursing and Midwifery Council during the consultation, the amendments to the Nursing and Midwifery Order 2001 were brought forward in a separate Order. (The Nursing and Midwifery (Amendment) Order 2008, which was laid before Parliament on 21 April).

The draft Health Care and Associated Professions (Miscellaneous Amendments) Order therefore no longer applies to the Nursing and Midwifery Council. Responses to the questions relating to the NMC were considered in "The Nursing and Midwifery (Amendment) Order 2008 – a consultation response" laid before Parliament on 21 April. These questions are therefore not considered in this response.

Consultation Process

The consultation took place over a three-month period between 22 November 2007 and 22 February 2008.

Respondents were requested to fill in a form and submit it either electronically or by post. A number of responses were made in the form of a general letter rather than replies to specific questions.

64 responses were received by the closing date, and a further 3 by the end of February. Although outside the time limit, the comments made in the late responses have also been noted.

The responses represented a diverse mix of bodies/organisations, individual professionals and members of the public. They included all the primary stakeholders in the field of healthcare professional regulation.

A table showing all the respondents is attached.

Specific issues which arose in relation to the questions

Question 1: Do you support having, as a main objective for all the regulators, a provision giving greater emphasis to the importance of public protection?

This was given nearly 90% support. However, it is clear from the comments received that the support was for the principle of giving greater emphasis to the need and importance of public protection, rather than for the wording of the provision itself. Most respondents found the wording of this provision to be overly complicated and therefore difficult to understand. In the light of those comments the Government has decided to withdraw the provision and will return to it at the next available opportunity.

Question 2: Do you agree that these standard duties will improve the co-operation and co-ordination between professional regulators and key stakeholders?

All regulators will be required to have a proper regard for the interests of persons using or needing the services of registered professionals. However, some respondents commented that these provisions did not go far enough in that the duty to co-operate did not require regulators to co-operate with or consult patient representative or professional organisations. The government has noted these comments. It supports the view that there needs to be greater patient and public involvement. It also recognises the important role that professional bodies have to play. However, it wishes to give further consideration to whether placing a duty on regulators to co-operate with patient representative or professional bodies is the best way forward. The Government will maintain its original proposals for the time being, look at the current requirements on consultation applicable to all the regulators and if appropriate bring forward further legislation at the next opportunity.

Q3 Do you agree that Parliament should play an enhanced role in relation to the monitoring of regulatory bodies, facilitated by improved arrangements for notification by the bodies of information relating to their past and future activities.

The overall response to this question shows 57% in agreement. Most respondents were unsure as to the benefit of this particular provision. The main concern expressed by these respondents was about the need for the regulatory bodies to be independent of government, and open and transparent in their processes. The Government agrees that the regulators should be independent of government, which is the main thrust of the reforms set out in this Order.

Q4 Do you agree with the new, more flexible arrangements for establishing constitutions for the regulatory bodies.

Most respondents supported the move towards setting out the constitution of the regulatory bodies in a separate constitution order. However, there was concern about the balance between lay and professional members.

The Government is taking forward legislation through the Health and Social Care Bill that would allow future Section 60 Orders to provide for the Councils of regulatory bodies to have a lay majority. However, this is only a facilitative measure intended to provide greater flexibility. Legislation will only be taken forward to create a council with a lay majority, if the regulatory body puts forward proposals itself.

The Government is working with each of the regulatory bodies to develop proposals for a new constitution to be made under this Order. A draft constitution order for the GMC was published for consultation on 16 May. Draft constitution orders for the other regulatory bodies will be published for consultation as soon as possible.

Q5: Do you agree with adding appearance on a barred list to the grounds for which a health professional's fitness to practise should be considered impaired.

This was given overall support. The regulatory bodies have rightly pointed out that the amendments set out in this order will not complete the process, and that consequential amendments will also need to be made to their Fitness to Practise rules, to allow decisions of the barring board to be treated in the same way as criminal convictions.

These amendments are also linked to changes to the Safeguarding Vulnerable Groups Act 2006 and the Protecting Vulnerable Groups (Scotland) Act 2007 set out in the draft Health Care and Associated Professions (Miscellaneous Amendments) (No. 2) Order 2008, which was published for consultation

between 21 December 2007 and 25 March 2008. The Government will therefore be bringing forward the necessary amendments to Fitness to Practise Rules as part of that Order.

Q6: Do you agree with the strategy for standardising the order and rule making powers of the regulators, and with the move towards giving them greater flexibility over internal processes while increasing Parliamentary scrutiny of outcome

The Government has decided to withdraw these provisions for further consideration.

Q7: Do you agree that all regulators of health care professions should be under a legal duty to maintain registers of the private interests of their council members.

This was given over 80% support.

Q8: Do you agree the regulators should have the option of engaging other bodies to assist them with their appointments functions

Overall support of over 80%. Some respondents raised issues on the need for the process of appointment to be impartial, open and transparent. The Government is clear that all appointments to regulatory bodies need to be made through a clear, open and transparent process.

Q9: Do you agree that the General Medical Council should be given reserve powers to register suitably experience people to help out as doctors during an emergency.

Most respondents supported this proposal. However, there was concern about the meaning on “suitably experienced” and the need to ensure patient protection. The Government has noted these concerns.

The proposed legislation are essentially reserve powers, which will provide options in the event of a major emergency such as an influenza pandemic. The provisions are deliberately drafted in such a way as to provide maximum reasonable flexibility. It is extremely difficult to determine in advance what precise measures will be required in an emergency. The GMC will have powers to impose conditions on registration and it will only be temporary.

Q10 Do you agree that the list of bodies that can provide primary United Kingdom medical qualifications should be an administrative list kept by the General Medical Council, and for which they are responsible, rather than being set out in statute?

Most respondents supported this proposal.

Q11 Do you agree that these UK trained Osteopaths who have been working overseas should have their qualifications recognised when they return to the UK, provided they apply within the stated time limits?

Most respondents supported this proposal. However, the General Osteopathic Council raised a number of concerns about the requirement for an osteopath to have practised for a period of at least three years as an osteopath outside the United Kingdom. Concerns were also expressed about the open nature of these provisions.

The provisions have now been amended to reflect these concerns. Applications under these provisions must now be made before 1 January 2011. No time limits are now given in relation to the period for which the applicants must have been practising.

Q12 Do you agree that these UK trained Chiropractors who have been working overseas should have their qualifications recognised when they return to the UK, provided they apply within the stated time limits?

Most respondents supported this proposal. However, there were a number of concerns about the requirement for a chiropractor to have practised for a period of at least three years outside the United Kingdom. Concerns were also expressed about the open nature of these provisions.

The provisions have now been amended to reflect these concerns. Applications under these provisions must now be made before 1 January 2011. No time limits are now given in relation to the period for which the applicants must have been practising.

Qs 13 and 14

These questions are about amendments to the Nursing and Midwifery Order. The amendments to this Order have been taken forward through a separate Order – The Nursing and Midwifery (Amendment) Order 2008 which was laid before parliament on 21 April. These response to these questions was considered in the response to the consultation published with that Order.

Annex A:

Health Care and Associated Professions (Miscellaneous Amendments) Order 2008 consultation questions and summary of responses

Matters affecting all regulators

Q1. Do you support having, as a main objective for all the regulators, a provision giving greater emphasis to the importance of public protection?

Q.1 Number of responses to question: 62			
	Agree	Disagree	Unsure
Number	55	4	3
%	89	6	5

Q2. Do you agree that these standard duties will improve the co-operation and co-ordination between professional regulators and key stakeholders?

Q.2 Number of responses to question: 62			
	Agree	Disagree	Unsure
Number	37	6	19
%	60	10	30

Q3. Do you agree that Parliament should play an enhanced role in relation to the monitoring of regulatory bodies, facilitated by improved arrangements for notification by the bodies of information relating to their past and future activities?

Q.3 Number of responses to question: 63			
	Agree	Disagree	Unsure
Number	36	16	11
%	57	25	18

Q4. Do you agree with the new, more flexible arrangements for establishing constitutions for the regulatory bodies?

Q.4 Number of responses to question: 61			
	Agree	Disagree	Unsure
Number	40	8	13
%	66	13	21

Q5. Do you agree with adding appearance on a barred list to the grounds for which a health professional's fitness to practise should be considered to be impaired?

Q.5 Number of responses to question: 62			
	Agree	Disagree	Unsure
Number	47	11	4
%	76	18	6

Q6. Do you agree with the strategy for standardising the order and rule making powers of the regulators, and with the move towards giving them greater flexibility over internal process issues while increasing Parliamentary scrutiny of outcome?

Q.6 Number of responses to question: 63			
	Agree	Disagree	Unsure
Number	43	9	11
%	68	14	18

Q7. Do you agree that all regulators of health care professionals should be under a legal duty to maintain registers of the private interests of their council members?

Q.7 Number of responses to question: 62			
	Agree	Disagree	Unsure
Number	54	7	1
%	87	11	2

Q8. Do you agree the regulators should have the option of engaging other bodies to assist them with their appointments functions?

Q.8 Number of responses to question: 61			
	Agree	Disagree	Unsure
Number	50	5	6
%	82	8	10

Amendments to the Medical Act 1983

Q9. Do you agree that the General Medical Council should be given reserve powers to register suitably experienced people to help out as doctors during an emergency?

Q.9 Number of responses to question: 54			
	Agree	Disagree	Unsure
Number	33	8	13
%	61	15	24

Q10. Do you agree that the list of bodies that can provide primary United Kingdom medical qualifications should be an administrative list kept by the General Medical Council, and for which they are responsible, rather than being set out in statute?

Q.10 Number of responses to question: 51			
	Agree	Disagree	Unsure
Number	30	8	13
%	59	16	25

Amendments to the Osteopaths Act 1993

Q11. Do you agree that these UK trained osteopaths who have been working overseas should have their qualifications recognised when they return to the UK, provided they apply within the stated time limits?

Q.11 Number of responses to question: 38			
	Agree	Disagree	Unsure
Number	24	2	12
%	63	5	32

Amendments to the Chiropractors Act 1994

Q12. Do you agree that these UK trained chiropractors who have been working overseas should have their qualifications recognised when they return to the UK, provided they apply within the stated time limits?

Q.12 Number of responses to question: 37			
	Agree	Disagree	Unsure
Number	22	1	14
%	59	3	38

Amendments to the Nursing and Midwifery Order 2001

Q13. Do you agree that the NMC should be given reserve powers to annotate their register so that suitably experienced persons without the relevant qualifications will nevertheless be able to act as prescribers of prescription only medicines during an emergency?

Q.13 Number of responses to question: 53			
	Agree	Disagree	Unsure
Number	27	14	12
%	51	26	23

Q14. Do you agree to allowing the NMC to determine who should sit on its practise committees?

Q.14 Number of responses to question: 54			
	Agree	Disagree	Unsure
Number	31	16	7
%	57	30	13

Annex B:

List of Respondents

Dr Ian Frayling	
Jane Pearson	NHS Blood and Transplant
Margaret Coats	General Chiropractic Council
Daniel Webster	Patient Liaison Group – Royal college of Surgeons
Duncan Forsyth	British Geriatrics Society
Jenny Higham	Imperial College London
Chris Derrett	
Oliver Dearlove	
Shaun Brookhouse	
Denice Wray	
Roisin Carruthers	
Wendy Scott	
Tahir Mahmood	Royal College of Obstetric and Gynaecology
Christopher Hallas	University College London
D Wieloch	
Alan Scally	
Mr MK Oak	
Nasim Mahmood	
Ros Tolcher	Southampton City PCT
Prof Paul Knight	Royal College of Physicians and Surgeons of Glasgow
Madeleine Anderson – Warren	British Association of Dramatherpists
Alison Highley	
Andrea Matthews	Community Health Councils in Wales
Ann Caldwell	Glodwick Health Centre
Claire Dent	
Ann Doveston	
Jane Naish	Royal College of Nursing
David Foord	NHS Direct
Carolyn Taylor	
I T Rowlands	
Prof Irving Taylor	Royal College of Surgeons of England
Suzanne Banks	Stoke on Trent PCT
Graeme Catto	General Medical Council
Mary-Lou Nesbit	Medical Defence Union
Alain Wainwright	Institute of Biomedical Science
*Sir Anthony Garrett	Association of British Dispensing Opticians
*Bob Hughes	Association of Optometrists
*Bryony Pawinska	College of Optomtrists
Susan Pirie	Association for Perioperative Practice
Prof Mike Greaves	University of Aberdeen
Jacqueline Foukas	British Medical Association
Peter Pinto	Nursing and Midwifery Council
Sushant Varma	
Evlynee Gilvarry	General Osteopathic Council
Jon Levett	General Optical Council
Terry Johnson	Voluntary Registration Council for Healthcare Scientists
Alison Ludlam	Wandsworth PCT
Peter Walsh	Action against Medical Accidents
Sally Aldridge	British Association for Counselling and Pscyhotherapy
Elaine Charters	Academy of Medical Royal Colleges
Dr Rodney Burnham	Royal College of Physicians
David Hewlett	Federation of Ophthalmic and Dispensing Opticians
Jan Armstrong	City Hospital, Sunderland, NHS Foundation Trust
Stephanie Croker	Medical Protection Society
Alastair Henderson	NHS Employers

Nick Bishop	Healthcare Commission
Richard Smith	Royal College of Ophthalmologists
Dr Philip Pearson	
Suzanne Rastrick	Dorset PCT
Gail Adams	Unison
Cheryl Adams	Unite – the Union

* joint response

Summary: Intervention & Options

Department /Agency:	Title:	
DH	**Impact Assessment of Health Care and Associated Professions (Miscellaneous Amendments) Order**	
Stage: Implementation	**Version:** 1.1	**Date: 30 May 2008**
Related Publications: White Paper: Trust, Assurance and Safety - regulation of healthcare professionals in 21st C (February 2007)		

Available to view or download at:
http://www.dh.gov.uk

Contact for enquiries: Stuart Griffiths **Telephone:** 0113 254 5249

What is the problem under consideration? Why is government intervention necessary?

Modernisation of the regulation of health care and associated professions:

Purpose of professional regulation is to ensure patient safety, set standards of competence for those registered and maintain a system to investigate and where necessary restrict or prevent practise by those professionals whose fitness to practise is called into question.

Government intervention is necessary to update and reform the system of regulation in order to maintain and improve public confidence

What are the policy objectives and the intended effects?

In order to exercise their functions effectively and command the confidence of patients, the public and the professions, the healthcare professions regulators need to be seen to be independent and impartial in their actions. This Order makes changes to the governing structures of the regulatory bodies, including a move to full appointed councils, and changes to make them more accountable to Parliament. This is intended to ensure that purely professional concerns are not thought to dominate their work.

What policy options have been considered? Please justify any preferred option.

The policy options were discussed in two consultation documents published in 2006: "Good doctors, safer patients" and "The Regulation of non-medical health care professions, a review by the Department of Health". The White Paper "Trust, Assurance and Safety - the Regulation of Healthcare Professionals in the 21st Century" set out a series of reforms based on the results of this consultation. This Order is part of a series to implement these proposals. Evidence base attached refers to the preferred option identified through that consultation.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? 2011

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Ben Bradshaw.....Date: ***2nd June 2008***

Summary: Analysis & Evidence

Policy Option:	Description:

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	
£ 0	
Average Annual Cost (excluding one-off)	
£ 107k to £500k	**Total Cost** (PV) **£ 0.48m to £2.26m**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	
£ 0	
Average Annual Benefit (excluding one-off)	
£ 0	**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' enhanced confidence in regulation through removing perception that professional interests dominate work of regulators, greater focus on patient safety in setting standards. Improved protection for vulnerable groups by allowing exchange of information between regulators and vetting and barring scheme

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				April 2008 onwards	
Which organisation(s) will enforce the policy?				GMC, GOC etc	
What is the total annual cost of enforcement for these organisations?				£	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£	
What is the value of changes in greenhouse gas emissions?				£	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)		Micro	Small	Medium	Large
Are any of these organisations exempt?		Yes/No	Yes/No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ Decrease of £ **Net Impact** **£**

Key:	**Annual costs and benefits: Constant Prices**	**(Net) Present Value**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Background

The UK Government's programme for reforming the regulation of all health care and associated professions was first set out in *The NHS Plan – A Plan for investment, a plan for reform.* This made clear that regulation should be strengthened and specified that regulatory bodies must change so that they

- are generally smaller, with much greater patient and public representation in their membership;
- have faster more transparent procedures;
- develop meaningful accountability to the public and the health service.

Although good progress has been made, the need for further reform was identified in the two reviews of professional regulation published for consultation in July 2006: *Good doctors, safer patients* by the Chief Medical Officer for England, and the Department of Health's *The regulation of the non-medical health care professions.*

The White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* set out a substantial programme of reform to the United Kingdom's system for the regulation of health care professionals, based on consultation on the two reviews mentioned above. It is complemented by *Safeguarding Patients,* the UK Government's response to the recommendations of the Fifth Report of the Shipman Inquiry and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries, which set out a range of measures to improve and enhance clinical governance in the NHS.

The draft Order is part of a series of Orders that will take forward the reforms identified in the White Paper. This Order concentrates on the reforms set out in Chapter One of the White Paper (*Assuring independence: the governance and accountability of the professional regulators)* but also includes measures that are required to deliver other legislative requirements and some items that have been identified by the regulators as needing urgent reform**.**

The reforms outlined in this Impact Assessment were set out in the draft Health Care and Associated Professions (Miscellaneous Amendments) Order which was published for consultation on 22 November 2007. The consultation closed on 22 February. There were 67 responses from a diverse mix of bodies/organisations, individual professionals and members of the public. They included all the primary stakeholders in the field of health care professional regulation.

The overall response was in favour of the reforms set out in the legislation. However the draft legislation has been amended to reflect comments received during the consultation. This impact assessment have been updated to reflect the outcome of the consultation. A report of the consultation will be laid in Parliament with the draft Order.

Temporary registration during emergencies involving loss of human life

The amendments proposed apply to the General Medical Council.

These amendments are required as a direct result of the Civil Contingencies Act 2004, which makes provisions for emergency regulations in a situation (such as pandemic illness) where there is substantial loss of life.

The amendments provide for the Registrar at the General Medical Council to direct that a person or specified group of persons may be registered as fully registered medical practitioners for the duration of the emergency.

Possible costs:

GMC for maintaining “emergency doctors list”, admin costs associated with registration

Some impact for retired doctors etc but will be no registration fee so individual costs kept to a minimum.

No guarantee of fitness to practise so some risk to patients but outweighed by need to ensure that patients can get drugs etc during emergency. Registration is only for emergency. Any doctor whose fitness to practise is called into question to be removed from emergencies list.

Will apply to limited range of professionals eg recently retired medical practitioners whose name has been removed from the register.

It is difficult to fully assess the potential costs and benefits of temporarily registering medical professionals until the nature and extent of any emergency is known. Estimates prepared in advance of Parliamentary scrutiny of the Civil Contingencies Bill suggest that compliance costs should be relatively insignificant.

Current GMC full registration fee charged to registrants of £290 includes admin costs of £42.71.

A full Regulatory Impact Assessment prepared for the Civil Contingencies Bill can be found at http://www.co-ordination.gov.uk/upload/assets/www.ukresilience.info/riav1.pdf

Estimated Costs:

Minimum cost of maintaining register = £42.71 (admin costs from GMC registration fee, other costs such as professional regulation/fitness to practice costs will not be relevant as temporary registrants will not practice unless in an emergency)

Maximum cost of maintaining register = £100 (includes potential additional costs of cross-referencing with previous GMC lists and criminal records checks if this is not included in admin costs).

Number of recently retired doctors = 10,000 over 5 years

Assume 25-50% of doctors that retired in the last 5 years may be willing for temporary registration = 2500 to 5000 doctors.

Minimum cost = 2500 x £42.71 = £106,775 per year

Maximum cost = 5000 x £100 = £500,000 per year.

General Medical Council to maintain list of approved medical qualifications

At present, the bodies entitled to hold qualifying examinations for granting primary United Kingdom qualifications are set out in the Medical Act 1983. If the Education Committee of the GMC agrees another examination or qualification meets the required standards it may apply to the Privy Council for it to make an Order adding that qualification to the list in the Medical Act. If the Education Committee is no longer satisfied that a qualification meets the required standard it must apply to the Privy Council to have that qualification removed from the Act. The only new bodies that can be listed are universities of combinations of universities

The proposed amendment would have four effects;

i) to transfer the responsibility for who is added to, or removed from, the list of approved bodies from the Privy Council to the General Medical Council

ii) remove the need for the qualifications to be set out in legislation

iii) allow bodies other than universities or combination of universities to be included in the list

iv) change the balance of responsibilities within the GMC so that the Council itself is responsible for maintaining publishing and amending the list

This amendments does not alter the process for the approval of medical qualifications, rather it simplifies the process for notification of approval once it has been granted. Under current arrangements once the GMC has approved a qualification it must seek Privy Council approval and make a statutory instrument amending the Medical Act adding the qualification to the approved list. Under new arrangements GMC will maintain list of approved courses without the need to involve Privy Council or make Statutory Instruments. Therefore cuts administrative burden on GMC, DH, DWP(SOL), Privy Council and Parliament.

This amendment also changes the reference in the Medical Act to qualifications provided by a “university” to “a body or combination of bodies”. This is to recognise developments in the provision of medical education which mean that some qualifications are provided in the United Kingdom by colleges or other bodies that are not recognised as Universities. This does not affect the function of the GMC approving such qualifications nor does it affect the requirement to have an approved medical qualification to be registered as a medical practitioner.

Relates to administrative arrangements for approval of qualifications. Limited savings in administrative costs.

Safeguarding Vulnerable Groups

The amendments proposed will add to the reasons that a persons fitness to practise may be considered impaired

i) the Independent Barring Board including a person in a barred list

ii) Scottish Ministers including a person in the children’s list or the adults’ list.

This will apply to the General Medical Council, General Optical Council, General Osteopathic Council, and the General Chiropractic Council. These amendments are linked to amendments made to the Safeguarding Vulnerable Groups Act 2006 put forward in the “Health Care and Associated Professions (Miscellaneous Amendments) No 2 Order” published simultaneously with this order.

The effect of the proposed new provisions would be that regulators would be able to take action against someone who appears on a barred list without needing to prove again the facts that led to a person appearing on that list. A similar approach is already undertaken with criminal convictions, where regulators are already able to take action without needing to prove the substance of the allegation that led to the criminal conviction. The amendments should help to

speed up the process for dealing with the practice of health care professionals who have already been the subject of an investigation that has led to serious adverse findings against them.

Improves patient safety by allowing free exchange of information between regulators and the vetting and barring scheme, and potentially speeding up process for dealing with health care professionals whose fitness to practise has been called into question.

A detailed regulatory impact assessment for the Safeguarding Vulnerable Groups Act can be found at:

http://www.everychildmatters.gov.uk/socialcare/safeguarding/independentsafeguardingauthority/

Annual Reports and Strategic Plans

These amendments update the provisions requiring regulators to produce annual reports and strategic plans. All regulators are currently required to produce annual reports which they send to the Privy Council. The amendments make further provision as to the content of these reports, including a statistical report which indicates the efficiency and effectiveness of its fitness to practise procedures, and information on how its has monitored the effects of its policies and activities on the diverse range of people they affect.

It will be a requirement that the regulator should lay a copy of its annual report and strategic plan before the UK, and (where appropriate) the devolved administrations.

All regulators already produce annual reports. The change therefore is to strengthen the accountability of the regulators to the public through Parliament and to the registrants who provide the bulk of a regulators funding.

No costs have been identified.

Composition of Councils

Chapter one of the White Paper Trust, Assurance and Safety puts forward a number of proposed changes to the size and structure of Councils. This includes a move to smaller, more board-like Councils with greater consistency of size and role across the professional regulatory bodies; parity of membership between lay and professional members as a minimum; council members to become independently appointed. A working group has been established to consider the overall governance arrangements for the regulatory bodies and is expected to report at the end of November 2007.

The amendments put forward in this Order will allow the Privy Council to provide by Order for the numbers of lay and registrant members on each council, their terms of office, arrangements for appointing a chair, and provisions with respect to the suspension or removal of members.

At present each Council consists of a number of lay members appointed by the Privy Council (who in practise delegate this task to the Appointments Commission) and a number of registrant members who are elected by the registrants themselves. In future all members of the Council will be appointed by the Privy Council.

Details of the membership, and constitutional arrangements for each of the regulatory bodies is set out in the governing legislation. The proposed amendments will remove the constitutional details from the primary legislation and provide for the Privy Council to set out this detail in an order. All organisations need to adapt to changing circumstances over time. These amendments will make it easier for changes to be made to a regulatory body's overall governing structure in the future.

No cost implications have been identified. It is estimated that each regulatory body will achieve savings through moving to smaller councils. The cost of appointing all council members is likely to be offset by no longer needing to hold elections.

A detailed impact assessment will be prepared in respect of each regulatory body when new constitutions have been developed and their constitution order is published for consultation.

Registration of member's private interests

This amendment will require all regulators to maintain a register of the private interests of their Council members. It is intended to improve patient safety by ensuring that Council members do not have any conflict of interest.

Minimal cost implications.

Duty of Co-operation and duty to consider the interests of stakeholders

The amendments here are intended to embed the duty of consideration of key stakeholders with an interest in the work of a regulator, particularly employers, education and training providers, healthcare system providers and managers. The current reforms of the health system are making stronger links between systems regulators and professions regulators and it is necessary that this is supported by a corresponding duty on all professions regulators to co-operate with and consider the interests of all stakeholders in their deliberations

Minimal cost implications.

Appointments to committees

This is a facilitative measure to allow regulatory bodies to make arrangements with another body for that body to assist the regulator in exercising its appointments functions. It is a facilitative measure giving greater flexibility to a regulator, especially to the smaller organisations who might not have the expertise or experience available to be able to exercise their appointment functions efficiently.

Admin function of regulator covered by running costs.

Continuing professional development

This is a minor amendment included at the request of the regulatory bodies. It applies only to the General Osteopathic Council and the General Chiropractic Council. The purpose is to recognise that further courses of training are not the only means by which a professional may maintain his professional expertise. The term "continuing professional development" would include courses of training.

Minimal cost implications.

Statutory Committees of the General Osteopathic Council, and General Chiropractic Council

A number of amendments are made to the provisions covering the statutory committees of these two organisations. These

- remove the requirement for Council members to be appointed to the Committees, (Osteopathic and Chiropractic Councils only)
- provide for the General Council to regulate the procedures of its committees through the use of Standing Orders rather than having to make rules approved by the Privy Council, improving the Council's independence, and
- remove detailed requirements for the membership, quorum and deputising arrangements for the chair from the legislation. In future the Council will be able to make provision for these aspects through the use of Rules, again increasing the Council's independence. For the NMC this will also apply to the Midwifery Committee.

Minimal cost implications.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	Yes
Small Firms Impact Test	Yes	Yes
Legal Aid	Yes	Yes
Sustainable Development	Yes	Yes
Carbon Assessment	Yes	Yes
Other Environment	Yes	Yes
Health Impact Assessment	Yes	Yes
Race Equality	Yes	Yes
Disability Equality	Yes	Yes
Gender Equality	Yes	Yes
Human Rights	Yes	Yes
Rural Proofing	Yes	Yes

Annexes

Competition Assessment

No issues have been identified

Small Firms Impact Test

No impact on small firms

Legal Aid

No legal issues identified

Sustainable development

No issues identified

Carbon Assessment

No impact

Other environment

No environmental issues identified

Health Impact Assessment

No issues identified

Race/Disability/Gender equality

In drafting the Order, and this consultation document we have considered the possible impact on equality issues (age, disability, gender, race, religion or belief, and sexual orientation) of each of the policies described in this Impact Assessment. It has been concluded that there is no impact, other than the benefit in requiring the regulatory bodies to report on these issues in their annual reports

Human Rights

No issues identified

Rural Proofing

No issues identified