

Summary: Intervention & Options

Department /Agency: DH	Title: 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 21 st C (February 2007)		

Available to view or download at:

<http://www.dh.gov.uk>

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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? June 2011

Ministerial Sign-off For consultation 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:

..... Date: May 2008

Summary: Analysis & Evidence

Policy Option:	Description:
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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) £
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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 or 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 amendment 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 person's 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	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
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

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