

The regulation of the non-medical healthcare professions

A review by the Department of Health



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Policy HR / Workforce Management Planning Clinical	Estates Performance IM & T Finance Partnership Working
Document Purpose	Consultation /Discussion
ROCR Ref:	Gateway Ref: 6856
Title	Healthcare Professional Regulation: Public Consultation on proposals for change
Author	Department of Health/Workforce Directorate/Professional Regulation Branch
Publication Date	14th July 2006
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs, Medical Directors, Directors of PH, Directors of Nursing, Local Authority CEs, Directors of Adult SSs, PCT PEC Chairs, NHS Trust Board Chairs, Special HA CEs, Directors of HR, Directors of Finance, Allied Health Professionals, GPs, Departments of Health for the devolved administrations
Circulation List	Communications Leads, Emergency Care Leads, Directors of Children's SSs, Voluntary Organisations/NDPBs
Description	This consultation document calls for a response to eleven themes covered by the two review reports attached – CMO's review of the arrangements for medical regulation <i>Good doctors, safer patients</i> and the departmental review <i>The regulation of the non-medical healthcare professions</i> .
Cross Ref	N/A
Superseded Docs	N/A
Action Required	N/A
Timing	Response to consultation by 10th November 2006
Contact Details	Professional Regulation Consultation Team, Department of Health, Room 2N35A, Quarry House, Quarry Hill, Leeds LS2 7UE www.dh.gov.uk/liveconsultations
For Recipient's Use	

Contents

Introduction	3
Summary of decisions	6
1. What does professional regulation mean today?	11
2. Demonstrating fitness to practise a profession – entering the register	15
3. Demonstrating continuing fitness to practise a profession – staying on the register	18
4. Resolving concerns about fitness to practise	25
5. Regulating staff with lower levels of qualification	31
6. Regulating new professional roles	35
7. The role, structure, functions, governance and numbers of regulatory bodies	38
8. Connections with CMO's report <i>Good doctors, safer patients</i>	44
9. Action Plan	46
Appendix 1 – Membership of the advisory group	47
Appendix 2 – Definitions	48
Appendix 3 – Regulatory Impact Assessment	51

Introduction

This document flows from the work of a review of non-medical professional regulation which was set up in March 2005 by the then Secretary of State, John Reid. It deals with the regulation of health care professionals other than doctors. This was a suitable moment to examine the effectiveness of professional regulation, five years after major changes which had seen the establishment of the Health Professions Council and the Nursing and Midwifery Council. The short-term origin of the review was however the need to respond to the Reports of the Shipman Inquiry and particularly, their comments on the GMC.

The Chief Medical Officer was already involved in a review resulting from the Inquiry's Fifth Report, which of course confined itself to the regulation of doctors. It is however essential that all the different healthcare professions, which work together so closely, are regulated in consistent ways which are planned together as an integrated whole. Our plans to do so are set out in this document and in CMO's report, *Good doctors, safer patients*, also published today. The system of professional regulation has fallen short of this standard in the past.

The non-medical review's terms of reference focus on ensuring proper protection of the public. It was charged with considering and advising the Secretary of State about the measures needed to:

- strengthen procedures for ensuring that the performance or conduct of non-medical health professionals and other health service staff does not pose a threat to patient safety or the effective functioning of services, particularly focusing on the effective and fair operation of fitness to practise procedures,
- ensure the operation of effective systems of continuing professional development (CPD) and appraisal for non-medical healthcare staff and make progress towards revalidation where appropriate, and to
- ensure the effective regulation of healthcare staff working in new roles within the healthcare sector and of other staff in regular contact with patients.

And in the light of these, it was to consider and recommend any changes needed to the role, structure, functions, governance and number of regulators of non-medical healthcare professional staff.

The Department of Health's Director of Workforce, Andrew Foster, was charged with carrying out the review and making recommendations. He was assisted by an advisory group, whose members are listed in Appendix 1. They included

representatives of patients, employers and professionals, as well as some of the regulatory bodies. Representatives of the other three UK Health Departments took part as well.

In addition to the advisory group, the review benefited from a reference group of around 100 members, which met in two conferences. The review received still wider and deeper input from the replies to a “call for ideas”. Over 100 responses were received, including views from significant groups representing patients, professionals, employers and regulators. The advisory group itself took a range of evidence including oral evidence from regulatory bodies and from Which? It specially commissioned research into public understanding and expectations of professional regulation and information about the regulation of staff in other sectors with safety-critical work, including in social care and education. The Department of Health also commissioned research about the regulation of health professionals in other countries which the group used in its work.

The work of the advisory group made a major contribution to the completion of the review. The group agreed that the prime purpose of regulation is to protect service users, and agreed that what regulation should do for service users is provide a system to ensure that staff working in healthcare are properly trained, up to date and fit (or competent) to practise. The advisory group also agreed a series of key definitions (attached as Appendix 2). It identified six principal strands of work and considered and discussed papers on each of these strands, with conclusions which reflected its majority views. These were:

- How to demonstrate initial and continuing fitness to practise
- Fitness to practise investigations
- Support workers and regulation
- New and extended professional roles
- How regulation supports its wider context
- Structure, functions, governance and number of regulators.

The advisory group offered advice on the more controversial areas where different options were considered.

Most aspects of the regulation of healthcare professions are reserved to Westminster, although there are some which are devolved to Scotland, Wales and



Northern Ireland. In general, the regulation of health professions covered in legislation existing before devolution is reserved, and the rest devolved to Scotland and Northern Ireland. Wales, like Scotland and Northern Ireland, is responsible for organising its own NHS provision. The review therefore involved the participation of senior officials from each of the UK countries, and the decisions in this report to that extent reflect the views of the government in each UK country.

No report on regulation would be complete without reference to the financial aspects. The total cost of professionally-led regulation in the UK – based on the budgets of the 9 regulatory bodies – is of the order of £100m to £120m. As the individual's registration fees are tax deductible, part of this burden falls on the taxpayer, but most is paid by the individual practitioners themselves. The burden of regulation on individual practitioners varies from £43pa (nurses) to over £1,000pa (chiropractors). This is partly because – generally – the larger the group being regulated the lower the individual fee (because of economies of scale) but also reflects the fact that some of the external cost pressures – such as the number of complaints being investigated and the costs of legal representation – vary between different regulatory bodies. The changes set out in this report could add around £35-50 million per year to the costs of healthcare in the UK but improvements in safety also bring significant cost savings, for example in accidents and injuries avoided.

Summary of decisions

Ministers have come to the following conclusions as a result of the review, subject to consultation.

1. Regulation of the professions should be co-ordinated with the regulation of health services; build on systems used by employers (and NHS commissioners) where possible; form one integrated and consistent framework of regulation across the different professions, in which departures from the standard approach need objective justification in terms of public protection; and adopt a risk-based approach, in which any new regulatory activities must be as simple and light touch as is consistent with their patient safety goals. (chapter 1)
2. Regulators should be more consistent with each other about the standards they require of a person entering the register for the first time, and employers and regulators should agree on common standards as far as possible. All regulators should adopt a single definition of “good character”, one of the legal requirements for getting registration. This should be based on objective tests. (chapter 2)
3. When a professional starts their first job they have to get onto a regulator’s register and satisfy the requirements of their employer. Employers and regulators should co-ordinate their information requirements so that the person provides each piece of information only once. (chapter 2)
4. Revalidation is necessary for all professionals. The regulatory body needs to be in charge of setting the standard which a person must meet to stay on the register. Information already collected by the employer/commissioner should be used to meet both their and the regulator’s needs. (chapter 3)
5. The revalidation system should be both formative (an aid to development) and summative (a check that a required standard is met). Within the NHS, information gathered under the Knowledge and Skills Framework (KSF) should be the basis of revalidation. Any additional requirements should be justified by risk analysis. Professionals will fall into one of three groups for revalidation:
 - employees of an approved body – revalidation carried out as part of the routine staff management or clinical governance system.



- self-employed staff providing services commissioned by NHS primary care organisations – revalidation processes built into the relevant NHS arrangements and carried out under the supervision of the commissioning organisation
 - all others – regulatory bodies develop direct revalidation arrangements. (chapter 3)
6. The Healthcare Commission in England (or its equivalent in each of the other UK countries) should approve employers who can deliver reliable revalidation processes. (chapter 3)
 7. In addition to information from existing clinical governance systems, further information will be needed for a reliable assessment that a person remains fit to practise. This should however be proportionate and based on risk assessment. (chapter 3)
 8. Post-registration qualifications should be recorded in the register where the specialisation is relevant to patient care and patient safety, can be defined in terms of extra skills acquired, and is at a level substantially beyond basic registration. (chapter 3)
 9. There should be a single source of advice to those who want to express concerns about registrants and a single investigation process at local level that would provide a report and evidence that would, where possible, meet the various needs such as resolving a complaint and deciding whether to refer to a regulator. Any investigation needs to determine what actually happened. (chapter 4)
 10. The Council for Healthcare Regulatory Excellence (CHRE) should organise the agreement of protocols for local investigation which would ensure that their findings of fact could be relied on by regulators if a case had to go to them for resolution. Their audit role should be extended to include a duty to sample decisions taken by regulators not to proceed to formal investigation of cases referred to them (chapter 4)
 11. Employers should remain ready to refer the most serious cases to the national regulator, that is, every case where investigation might lead to removal from the register. (chapter 4)

12. The task of adjudicating on concerns about impaired fitness to practise should be carried out either (a) by a single separate adjudicator for all the professions; (b) as now for the non-medical professions, or (c) under the control of regulators as now, but by shared panelists working to common standards. Comments are invited on this.
13. Each panel hearing a case about fitness to practise would include lay and professional members; the latter selected with regard to the area in which the person appearing was working. (chapter 4)
14. The Scottish pilot of employer-led regulation of support workers, which should provide important evidence about whether this is the best way to proceed, will continue until the end of 2006. A successful outcome for the pilot could lead to the adoption of a UK-wide employer-led approach to the regulation of this group of workers. (chapter 5)
15. The new roles using the working titles of Anaesthesia Practitioner, Emergency Care Practitioner, Endoscopy Practitioner, Medical Care Practitioner and Surgical Care Practitioner need statutory regulation, if healthcare providers agree they are fit for purpose. Work remains to be done about the exact form this should take: whether they should be regulated as one group with specialisms, or as up to five separate groups. (chapter 6)
16. One or more existing regulators will become the “lead regulator” for new groups. The lead regulator will set the standards applying to everyone registering as a member of the new group. Where someone joins the new group from an existing profession, they can remain registered with their existing regulator and avoid costly dual registration. (chapter 6)
17. All regulators have the same role of protecting the public. Where existing legislation adds other roles of professional leadership and promoting the profession, as for example in pharmacy, these should be explicitly and exclusively exercised for the public benefit. The implementation of changes following this review will provide opportunities to bring the regulation of these professions into line with the majority. (chapter 7)



18. There are substantial areas in which common standards would be desirable – in particular most aspects of conduct. The more difficult task of identifying common educational standards in areas such as the knowledge needed to underpin safe prescribing should not be ducked either. The regulators and CHRE should work to introduce common standards in all those areas where this would benefit patient safety. (chapter 7)
19. Some or all of the elected professional members of Councils should be replaced by appointed professional members. A clear person specification is required, identifying desirable qualities. Professional majorities on each regulatory body could remain, but they should in future be made up differently, with most or all professionals appointed rather than elected. (chapter 7)
20. Comments are invited on the future balance of Councils between professional and lay members, with the possibility of either a professional majority of one, a lay majority of one or no change. (chapter 7)
21. Changes are needed to the membership of CHRE's Council which will preserve its lay majority (and UK-wide makeup) while securing a professional voice through appointments against objective criteria, in place of the existing *ex officio* membership of Regulatory Bodies' Presidents. (chapter 7)
22. A regulator like the Health Professions Council, dealing with a range of disparate professional groups, can deliver the functions which public protection requires. Professional bodies dedicated to providing leadership and setting standards are also needed: the two work together. (chapter 7)
23. Any new profession coming into statutory regulation should be regulated by one of the existing regulatory bodies, most likely the HPC. (chapter 7)
24. The Pharmaceutical Society of Northern Ireland (PSNI) should remain as an independent body for the time being but with shared functions with the Royal Pharmaceutical Society of Great Britain (RPSGB). In the longer term, however, the two societies should amalgamate into a single UK body, following the passage of the necessary primary legislation. At the same time any necessary changes can be made to clarify the separation of the RPSGB's regulatory and professional lead functions. However there should be no other changes to the number of regulators at present. (chapter 7)

25. We will keep under review the question of whether harmonisation of the work done by the remaining regulators delivers the necessary benefits or whether this requires a further cut in the number of regulatory bodies. We will review the position after five years, in 2011. It may be that in practice the need for further structural change can be avoided by closer collaboration and harmonisation between all the remaining regulatory bodies. (chapter 7)

Chapter 1: What does professional regulation mean today?

1. From the outset of the review, we have defined regulation as the set of systems and activities intended to ensure that healthcare practitioners have the necessary knowledge, skills, attitudes and behaviours to provide healthcare safely (appendix 2 contains definitions of key terms). The goal of professional regulation is patient safety.
2. This means professional regulation needs to:
 - set and promote those standards which, for reasons of safety, everyone in a profession (or branch of a profession) has to meet
 - publish a register of those who meet these standards, and
 - ensure that everyone on the register continue to meet the standards, both by periodic checks for all and by procedures for resolving concerns which a complaint or incident might create.
3. Professional regulation becomes statutory regulation at the point where the State regards it as so important for public safety that it legislates for a ban on either using the professional title or doing certain things unless your name appears in the register. This protects patients from the harm caused by people practising a profession which they are not fit to. It engenders public confidence by allowing members of the public and the employers of professionals to check on a person's registration status, knowing that the information they find will be correct and up to date.
4. In passing, we should clarify that this does not make regulation a mere process of weeding out people who fall short of a standard. A balance needs to be struck between doing this and promoting higher standards for all. For regulation to motivate and engage with the majority who always aim to practise safely, it must aim for improvement, not mere compliance.
5. Regulation does not take place in a vacuum however and the rest of this chapter notes some relevant context which affects the way it needs to function in the UK today.
6. Most important of all is the worldwide movement in the last generation to measure and improve the quality of health services. The connection between professionals who are fit to practise and services of adequate quality is obvious. We now have systems to monitor the performance of NHS and private providers of healthcare: in England and Wales, the Healthcare

Commission and Health Inspection Wales; in Scotland, NHS QIS and the Scottish Commission for the Regulation of Care, and in Northern Ireland, the Health and Social Services Regional Improvement Authority. NHS organisations have a statutory responsibility for quality of services. The need for the right interfaces between these regulators of organisations and the regulators of individuals is widely acknowledged.

7. Most health professionals are now employees, a fact which is insufficiently recognised by the existing approach to professional regulation. (An important minority are of course self-employed.) The NHS remains very much the largest employer, but the diversity of employment in healthcare is increasing. Commercial firms employ significant numbers of nurses, pharmacists and other health professionals and this trend will continue. Many primary care professionals – GPs being the obvious example – have nationally negotiated arrangements with the NHS to perform services although they are not its employees. Employers (and the commissioners of NHS primary care) need their own assurance about the quality of each professional's work. So the system of regulation needs to recognise employers' particular needs and the contributions they can make, in order to deliver public protection most efficiently and effectively.
8. A third contextual factor is the diversification of clinical services. Professionals now work in more diverse services than ever before. Innovation produces ever more forms of professional activity. Sometimes it breaks down barriers between professions whose members used to work in very different ways. Conversely, it can also produce ever-greater specialisation. Completely new workforce roles arise and raise the question of how they will be regulated (which is discussed in chapter 6).
9. Fourth, devolution has meant that the four countries of the UK have more scope to work out different approaches to NHS service delivery than before, more matched to specific needs. A UK-wide approach to regulation remains desirable in the interests of simplicity and mobility, but it also needs to be flexible enough to achieve its goal in all parts of the UK.



10. Fifth, public perceptions continue to be important. Research we commissioned from MORI showed that there is a high level of satisfaction with medical and non-medical professionals, but little public understanding of how they are regulated. There is strong public support for regular checks being carried out on non-medical healthcare professionals, as there is with doctors, and many thought, incorrectly, that this already happened. Most wanted to see assessments take place every couple of years. There was strong support for the idea of using patient feedback as a component of assessment.
11. Sixth, a discussion of the context would not be complete without a mention of the European Community. Free movement of professionals increases opportunities for service delivery and career development, but also poses some challenges to regulation. The UK must legislate within the constraints of the Treaties and relevant Directives, which provide for automatic recognition of the registration decisions of other Member States. A major Directive which codifies previous European law in this area has to be implemented by October 2007.
12. Discussion of regulation generally has become more sophisticated in recent years. The government's Better Regulation Executive (formerly Better Regulation Task Force) now expects all statutory regulation to be:
 - **Proportionate:** Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.
 - **Accountable:** Regulators must be able to justify decisions, and be subject to public scrutiny.
 - **Consistent:** Government rules and standards must be joined up and implemented fairly.
 - **Transparent:** Regulators should be open, and keep regulations simple and user friendly.
 - **Targeted:** Regulation should be focused on the problem, and minimise side effects.
13. These requirements apply to the regulation of health professions as much as they do to other kinds of regulation.

14. The 2005 Review therefore looked at how much of the existing system should be retained and at what needed to be changed. Its recommendations amount to a vote of confidence in the fundamentals: statutory regulation of professionals by bodies which are independent of government and with a leading role for members of the professions. The rest of this Report sets out the areas in which improvement is needed and the Government's decisions about how to bring it about.
15. As a result of the considerations set out in this chapter, the main themes are that regulation of the professions should:
 - be co-ordinated with the regulation of health services;
 - build on systems used by employers (and NHS commissioners) where possible;
 - form one integrated and consistent framework of regulation across the different professions, in which departures from the standard approach need objective justification in terms of public protection, and
 - adopt a risk-based approach, in which any new regulatory activities (revalidation in particular) must be as simple and light touch as is consistent with their patient safety goals.

Chapter 2: Demonstrating fitness to practise a profession – entering the register

Summary:

- **Regulators should be more consistent with each other about the standards they require of a person entering the register for the first time, and employers and regulators should agree on common standards as far as possible**
 - **All regulators should adopt a single definition of “good character”, one of the legal requirements for getting registration. This should be based on objective tests**
 - **When a professional starts their first job they have to get onto a regulator’s register and satisfy the requirements of their employer. Employers and regulators should co-ordinate their information requirements so that the person provides each piece of information only once.**
1. This chapter deals with how someone should prove their initial fitness to join a profession. Chapter 3 covers the more complex question of how they should subsequently prove that they remain safe to practise.
 2. Demonstrating fitness to practise begins, obviously enough, with securing an educational qualification recognised by the regulatory body. The setting of educational standards was outside the remit of the review and in any case did not appear to give cause for concern. It is worth noting just how important this process is, nonetheless. It is largely from their pre-registration education that members of professions derive the professional standards, attitudes and behaviours which normally protect patients effectively. Setting the necessary standards and verifying that education providers and students meet them is the heart of professional regulation, though it normally attracts little public attention.
 3. Most (though not all) health professionals begin their career as employees. At the point where their career begins, they simultaneously have to satisfy a regulator and an employer of a number of things. The review found that these requirements could be harmonised more than they are today.
 4. The different regulatory bodies have similar, though not identical, requirements of people seeking new registration. They require evidence that a new registrant is fit to practise, mostly in terms of health, “character” and training.

In response to a government initiative, indemnity insurance is also becoming a requirement over time. What is needed most now is a further effort to identify a common approach to the issue of “character”.

5. It has not always been very clear what the requirement for a professional to be “of good character” meant. It was put to the review that the whole concept was unhelpful and that the emphasis should be placed instead on conduct – the outward expression of a person’s attitudes. At the moment there are a variety of checks on character which have grown up in an uncoordinated way. NHS employers are subject to rules about taking up references (and giving them), and the health sector as a whole requires checks with the Criminal Records Bureau (CRB), whose role will be enhanced by the Safeguarding Vulnerable People Bill in response to the recommendations of the Bichard Inquiry.
6. Checking on a person’s character should be based on objective tests such as the absence of criminal convictions, adverse decisions by regulatory bodies, the information about likely criminal activity contained in an enhanced CRB disclosure and so on. While it is clearly a good thing that standards for pre-registration education should include the promotion of suitable attitudes, finding objective (and fair) ways to test these is much harder and we may need to satisfy ourselves with only testing what can be objectively measured.
7. There is work at European level to promote information sharing on the ‘good character’ of professionals who cross national borders, and this impetus should continue. CHRE is developing work on the definition of good character. This should continue and should receive regulators’ full support with a view to early adoption of a single standard.
8. As well as harmonising the information requirements, we should streamline the collection mechanisms so that the professional provides the information only once, where possible. It ought to be possible to arrive at a package of information and evidence which a person can provide just once to a single organisation, whether employer or regulator, who then assures others who need it that the information has been received and validated as necessary. The complexity of achieving that, however, should not be underestimated. Regulators are legally required to collect information at present and if some of this is delegated, it should be clear who is accountable for the quality of the information and how this will be checked. These legal issues will need



resolution. Such evidence is of course only valid for initial registration: issues about continuing checks afterwards are discussed in the next chapter.

9. In an attempt to simplify the recording of evidence about the suitability of staff, some NHS Trusts in England are piloting a credentialing system for junior doctors using smart cards. In this trial, credentialing means that the card contains essential data about eg occupational health and GMC registration, which allows the hospital to let the doctor start work. If the pilot is successful, it might be rolled out to non-medical staff and could be integrated with the developing Electronic Staff Record (ESR). The ESR is part of the NHS National Programme for IT in England and will replace dozens of separate current HR and payroll IT systems. ESR is now being piloted and is due for complete rollout in the NHS in England and Wales by 2008.
10. In a similar way, the Scottish Workforce Information Strategic System (SWISS) will implement a national workforce information database with a common set of data. Over the next 3 – 5 years, an integrated / interfaced Human Resources/ payroll system for NHS Scotland will be procured.
11. These technical developments may well offer new opportunities for NHS employers to share agreed data sets easily and yet securely with regulatory bodies. The NHS Connecting for Health programme should explore the potential for this at an early enough stage to influence the content of the 2008 version of the ESR.

Chapter 3: Demonstrating continuing fitness to practise a profession – staying on the register

Summary:

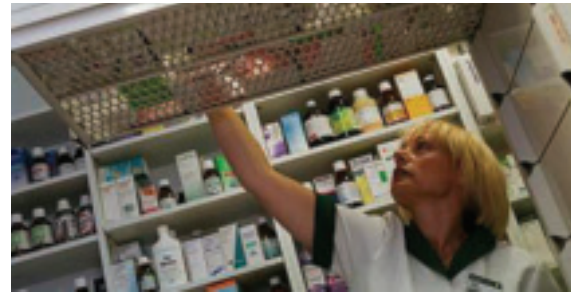
- Revalidation is necessary for all professionals
- The regulatory body needs to be in charge of setting the standard which a person must meet to stay on the register.
- information already collected by the employer/commissioner should be used to meet both their and the regulator's needs.
- The revalidation system should be both formative (an aid to development) and summative (a check that a required standard is met).
- Within the NHS, information gathered under the Knowledge and Skills Framework (KSF) should be the basis of revalidation. Any additional requirements should be justified by risk analysis.
- Professionals will fall into one of three groups for revalidation:
 - i. employees of an approved body – revalidation carried out as part of the routine staff management or clinical governance system.
 - ii. self-employed staff providing services commissioned by NHS primary care organisations – revalidation processes built into the relevant NHS arrangements and carried out under the supervision of the commissioning organisation
 - iii. all others – regulatory bodies develop direct revalidation arrangements.
- The Healthcare Commission in England (or its equivalent in each of the other UK countries) should approve employers who can deliver reliable revalidation processes.
- In addition to information from existing clinical governance systems, further information will be needed for a reliable assessment that a person remains fit to practise. This should however be proportionate and based on risk assessment.
- Post-registration qualifications should be recorded in the register where the specialisation is relevant to patient care and patient safety, can be defined in terms of extra skills acquired, and is at a level substantially beyond basic registration.



1. In the traditional model of professional regulation, a person remained on the register once he or she had passed the initial test, unless some definite reason came to light why his or her name should be removed. Research done for the review by MORI confirms that the public now expects periodic checks to show that a person remains safe to practise. Following the GMC's practice, these checks will be referred to as "revalidation". For doctors, the Shipman Inquiry said, "revalidation should comprise an evaluation of an individual doctor's fitness to practise." This review has concluded that everyone subject to professional regulation should in future have to revalidate, though different groups might do it in different ways and with different frequencies. This chapter makes initial recommendations about how revalidation should be carried out for all non-medical healthcare staff.
2. The regulatory body needs to be in charge of setting the standard which a person must meet to stay on the register. However, as discussed in chapter 1, a large number of registered professionals have an employer who also needs assurance that its staff are fit for the work they need to do. And many others work under nationally negotiated NHS arrangements in primary care. This puts them in a quasi-contractual relationship with an organisation with interests very similar to an employer. It would be a missed opportunity not to use the "quality assurance" information already being generated in these situations for the dual purpose of meeting the employer's (or commissioner's) and the regulator's needs. Where there is no employer or commissioner, or one which is not able to meet external standards for its own HR systems (perhaps a very small employer for example) then the information would still need to pass directly from registrant to regulator.
3. The next few paragraphs discuss arrangements already in place in the NHS. Appraisal was introduced for doctors in 2001. It is largely formative, and this gave the Shipman Inquiry some difficulty in accepting that it could be the basis, on its own, of satisfactory revalidation. All other professional staff are covered by Agenda for Change, which includes provision for appraisal. The government's plans for appraisal (which have not yet been implemented) place it within the part of the Knowledge and Skills Framework (KSF) called

Development Review. The main purpose of the KSF is to provide an NHS-wide framework that can be used consistently across the service to support:

- Personal development in post
 - Career development
 - Service development.
4. The development of appraisal for Agenda for Change staff will bring in the discussion of objectives linked to service and organisational needs, and development required for recertification/revalidation where appropriate. Further work will depend on the findings of this review.
 5. The NHS KSF is designed to identify the knowledge and skills that people need to apply:
 - In their post
 - To help guide development
 - To provide a fair and objective framework on which to base review
 - To provide the basics of pay progression in the service.
 6. The KSF is a broad generic framework that focuses on the application of knowledge and skills – it does not describe the exact knowledge and skills that people need to develop. Linked to the KSF, the National Occupational Standards (NOS) produced by Skills for Health have been praised for producing a consistent basis across the UK for describing particular competences. NOS are a useful currency in which to talk about competences and should be used in regulation where they are available.
 7. All staff will have annual development reviews, which will include appraisal, assessment against the KSF and the production of a Personal Development Plan using the KSF as a development tool. All four Government Health Departments are developing appraisal systems integral to the KSF Development Review based on a wide range of good appraisal practice which currently exists in NHS organisations such as PCTs and Trusts in England. The KSF began to roll out in October 2004 for NHS staff in England and will be fully implemented for all 1.2 million staff by October 2006. The KSF does not assume everyone has all the skills needed for their post on day one, but instead has a “First Gateway” for pay purposes which people should pass after about a year in post.



8. Within the NHS, information gathered under the Knowledge and Skills Framework (KSF) should be the basis of revalidation. Any additional requirements (discussed at paragraphs 13-14) should be justified by risk analysis. CMO's report *Good doctors, safer patients* envisages an important role in revalidation for a new group of local GMC "associates". One option for delivering revalidation with non-medical groups could be to extend this idea of associates. We would however welcome regulators' own views about the best way to deliver revalidation on the ground, based on their assessment of the levels of risk in different professions and settings, and other solutions might also be possible.
9. Professionals will fall into one of three groups for revalidation:
 - employees of an approved body – revalidation carried out as part of the routine staff management or clinical governance system.
 - self-employed staff providing services commissioned by NHS primary care organisations – revalidation processes built into the relevant NHS arrangements and carried out under the supervision of the commissioning organisation
 - all others – regulatory bodies develop direct revalidation arrangements.
10. There are other challenges which need to be met: the KSF has been designed to be used formatively and parts would need to be used as a summative tool. The use of the KSF is a matter of collective agreement and its development would need to be an agreed process.
11. There needs to be a system for checking that the employer or commissioner is able to produce reliable information. The Healthcare Commission (HC) in England (or its equivalent in each of the other UK countries) should as part of its annual assessment process determine that employers can deliver reliable revalidation processes. Following the HC's existing working methods, the process would involve:
 - The HC and equivalents publishing criteria (agreed with CHRE and regulatory bodies) for employers
 - an internal self-assessment by the employer against the standards, and
 - an external check – on a random and also a risk-assessed basis – by the HC as part of its Annual Health Check.

12. The HC criteria would underpin the relevant Core Standards in the Government's Standards for Better Health. In order for any employer or commissioner, in the NHS or otherwise, to satisfy the criteria and therefore to meet the core standards they would have to demonstrate that they had established their own appropriate system to revalidate their employees and/or contractors and their personnel.
13. This would provide a relatively streamlined route for securing much of the data needed for revalidation. However, as the Shipman Inquiry has already commented in relation to doctors, this information on its own may fall short of what is needed for a worthwhile reassurance that a person remains fit to practise. A further layer may need to be added. The challenge is to do this in a way which is proportionate to the risks posed by a person's professional practice, and avoids over-burdensome regulation.
14. More work is necessary on meeting this need for a more objective test of continuing fitness to practise. Crude measures could include complaints and negligence claims but these may not be sufficiently sophisticated. There will be lessons to be learned from the credentialing of doctors in other countries, such as the USA. Practical options will be identified and discussed further with the professions, patient groups and employers. Some professions may already operate voluntary "accreditation" schemes which the law could recognise as one route to revalidation.
15. The "intensity" of revalidation (how much information is needed and how often) should vary depending on a risk assessment. Risk factors to be considered include:
 - how likely it is to find impaired fitness to practise in this group of staff
 - how much impact impaired practice would have in this group.
16. Further consideration of this risk-based approach is needed. The following table illustrates a number of factors considered relevant to risk. The Canadian sift-based system may be one possible approach. This system enables targeting based on risk scores, and factors such as age and working environment are taken into account.



17. We conclude this chapter with a brief reference to the separate (though related) area of specialisation. As professionals specialise, the register should provide more information about post-registration qualifications. Some regulators already make marks in their Registers to record these. The main issues here are:

- what level of post-registration qualifications is it useful/necessary to record for patient protection purposes? Marks in the register should only be made where the specialisation is relevant to patient care and patient safety, can be defined in terms of extra skills acquired, and is at a level substantially beyond basic registration. Work at Band 7 of Agenda for Change or its equivalent (for example a specialist physiotherapy team leader in a stroke unit) ought to be the threshold. (Initial registration indicates that a person is normally working at around levels 4-6 with the majority at level 5.)
- once such a qualification or specialisation was recorded, revalidation would need to apply to the specialty as well as to basic registration. In this way an optometrist prescriber, for example, would demonstrate that they remained fit to prescribe as well as fit to work as an optometrist.

Table: Risk factors to consider in deciding the intensiveness of revalidation

HIGHER	LOWER
High level of responsibility for patient safety inherent in scope of practice	Low level of responsibility for patient safety inherent in scope of practice
Leaders of clinical teams	Team members
People who practise outside managed environments such as a hospital or clinic	People who practise within such environments
People whose working environment is not subject to NHS standards of clinical governance	People whose working environment is subject to NHS standards of clinical governance
Practitioners who are frequently alone with patients/clients (including in their homes)	Practitioners who always work in a team/do not work face to face with patients/clients
Unsupervised practitioners/posts	Supervised practitioners/posts
People in their first few years of registration (and possibly also their last few, according to some evidence)	Registrants in mid (or late?) career
Recent adverse finding by a regulator	Clean regulatory record
Recent appraisals show concern about performance	Good performance record
People who are in current practice	People who are not practising (some regulators have proposed a scheme where non-practising registrants need not revalidate at all) Those who are not practising should not be required to revalidate as there is no risk to the public. This does however have implications for re-entry to the register.
People using invasive, high-risk interventions	People using lower-risk interventions

Chapter 4: Resolving concerns about fitness to practise

Summary:

- there should be a single source of advice to those who want to express concerns about registrants and a single investigation process at local level that would provide a report and evidence that would, where possible, meet the various needs such as resolving a complaint and deciding whether to refer to a regulator.
 - CHRE should organise the agreement of protocols for local investigation which would ensure that their findings of fact could be relied on by regulators if a case had to go to them for resolution. Their audit role should be extended to include a duty to sample decisions taken by regulators not to proceed to formal investigation of cases referred to them.
 - Employers should remain ready to refer the most serious cases to the national regulator, that is, every case where investigation might lead to removal from the register.
 - The task of adjudicating on concerns about impaired fitness to practise should be carried out either (a) by a single separate adjudicator for all the professions; (b) as now for the non- medical professions, or (c) under the control of regulators as now, but by shared panelists working to common standards. Comments are invited on this.
 - Each panel hearing a case would include lay and professional members, the background of the professional ones chosen with regard to the area in which the person appearing was working.
1. Regulation requires processes to test a specific doubt that a registrant remains fit to be on the register – that is, fit to practise. For example, the registrant might have been convicted, or accused, of a serious crime, or the regulator might have received an allegation. For convenience, these processes are called the “fitness to practise system.” Broadly speaking, it has 4 main elements:
 - A complaint against, concern about or report received about a particular practitioner’s fitness to practise
 - Investigation
 - Adjudication, with the imposition of sanctions where these are found necessary
 - Appeal.

This chapter discusses desirable changes to make the fitness to practise system protect the public better. These changes would also give the public greater confidence in the system.

2. The present legal framework is designed to produce a fair decision about whether or not a registrant's fitness to practise is impaired, and if so to provide an appropriate and proportionate remedy for the protection of the public and maintenance of confidence in the profession. It is not a complaint resolution system, though some complainants mistake it for one. Fitness to practise (FtP) systems have become complex and highly legalistic, in order to comply with Human Rights considerations for the person accused, and to guard against successful legal challenge (including judicial review). There has been increased media/public interest in the FtP process (investigations & adjudications) as a result of the high profile cases such as Bristol, Alder Hey, Shipman and Allitt. The link between local complaints, employment disciplinary, criminal prosecutions, civil litigation and professional FtP cases has been under the spotlight more recently, as complainants try to decide which is the most appropriate route for resolution of their complaint.
3. Current FtP systems have real strengths which should not lightly be discarded. It would be possible to strengthen patient protection however by building on these strengths.

General issues

4. There are a number of general issues: to begin with, FtP systems are sometimes perceived as intimidating or unresponsive to members of the public who make a complaint. Some regulators have adopted good practices such as:
 - witness care schemes,
 - a helpline where staff can take details on the telephone and turn it into a statement for the complainant to sign, and
 - better information for complainants.

These could be used as best practice and adopted by other regulators.



5. The different FtP systems are inconsistent with each other. A doctor and a nurse involved in the same incident may find their cases being handled in different ways, which is confusing to the patient who has referred the matter to the regulator. A major legislative effort to bring the different pieces of law into line will be completed in the next 6 months. This will go a long way to ensure greater consistency (giving regulators, for example, access to the widest range of possible sanctions), but it will not eradicate inconsistency entirely. CHRE has started some work on convergence in FtP and indicative sanctions guidance which will address some of these issues.
6. It can also be reasonably claimed that there is too much law in this field. When nine regulators have separate FtP systems which each require Rules made under different Acts of Parliament, and these need amendment from time to time to close loopholes or reflect new policy, the result is a small cottage industry which is inefficient at producing good quality, consistent law. This increases costs, as solicitors and barristers who work for a number of regulators (as prosecutors, defenders, or legal assessors) in FtP cases have to be familiar with a range of different FtP law. This all adds to overall FtP costs. Problems have arisen in developing the law because of changing goalposts and there is a need to ensure consistency in drafting.

Initial notification of concern

7. Turning to the first stage of the process, the notification or raising of a matter of concern or a complaint, complainants would benefit from having a single source of advice (perhaps a portal on a website and/or telephone service) which would help them decide whether they wanted to make an NHS complaint, a complaint to a private resolution procedure such as the General Dental Council (GDC) and General Optical Council (GOC) are setting up, take civil legal action, institute criminal proceedings, or refer a professional to a regulator. DH is considering the idea of a "single portal" separately as part of its work on the complaints system, in response to the recommendation made in the Fifth Report of the Shipman Inquiry.
8. Discussion elsewhere has suggested that complaints data could be a fruitful source of information to improve patient services – emphasising the need for effective data sharing between regulators and employers.

Investigations

9. Moving on to the investigative stage, there is a degree of duplication with employers' disciplinary and complaints procedures. If a professional is investigated by their employer for misconduct, there may well be a parallel investigation by the regulator, albeit asking different questions and perhaps using different evidential standards. The same problem can arise in a performance or health case. There should be a single investigation at local level that would provide a report and evidence for these different purposes. An investigation needs to determine what actually happened and communicate this to the complainant before a judgment is made about what action then needs to be taken. Were this to happen, complainants would be able to receive explanations and apologies (without prejudice) soon after a complaint is lodged. This demonstrates action and taking the complaint seriously, and is likely to act to reduce the frustration of the complainant. Expertise would be needed at local level which may not always be there at present. Due process is important to withstand legal challenge, and the initial investigation needs to be done to the right standard. CHRE should organise the agreement of protocols for local investigation which would ensure that their findings of fact could be relied on by regulators if a case had to go to them for resolution.
10. Concern has been expressed about the risk to the public if issues are dealt with by employers without information going to regulators, when it is they who should more appropriately be taking action. Employers should remain ready to refer the most serious cases to the national regulator; that is, every case where investigation might lead to removal from the register. Work is already in hand to determine the thresholds at which regulators would accept referral of cases from PCTs and this could usefully be integrated into the development of the protocols called for in the preceding paragraph.
11. It might be possible to introduce a threshold of seriousness below which all cases had to be resolved locally, somewhat in the way that the Nursing and Midwifery Council (NMC) tries to deal with professional performance cases now. The GMC has recently announced that it will refer certain complaints back to the NHS employer for local resolution. If this pattern was generally adopted, there needs to be a way to identify worrying patterns of low-level problems and pick them up, also bearing in mind that using low-level cases to inform learning, policy and research is also valuable. Currently there is no



scrutiny or challenge to the process of determining which cases should proceed to adjudication – CHRE’s responsibilities should be extended to include audit (possibly on a sample basis) of the initial investigative stage, before a decision is taken formally either to drop or investigate a particular complaint, to ensure that the decisions taken fully reflect the need to protect patient safety.

Adjudication

12. In relation to adjudication, consideration has focused on the implications of the Shipman Inquiry’s 5th Report recommendation that this function be separated from the other functions of the regulator, primarily on grounds of equity. A recent judgment in the House of Lords suggests that the present system may well not be compliant with human rights legislation and there is concern that the regulator should not be prosecutor and judge in its own courtroom, for which it has written the rules and criteria to be followed by the participants. If the regulator is perceived to be inclined to favour its registrants, there is suspicion that judgments will be too lenient and will not secure either safety or trust. If the regulator is seen as biased against registrants, they will feel the results to be unfair. Currently regulators exhibit a range of different approaches with some having Council members participating in adjudication panels whilst others have enforced a clear separation.
13. These considerations lead to the following options for improvement, bearing in mind that CMO’s report *Good doctors, safer patients* recommends a new tribunal separate from the GMC to deal with cases involving doctors. Comments are invited on these three possibilities:
 - a. A single, separate adjudicator for all regulators – which would ensure a consistent, fair approach across all staff who often work together in teams.
 - b. A separate adjudicator for doctors whilst preserving current arrangements for the other professions – which would change the arrangements where they have proved inadequate.
 - c. A third way where all regulators (including the GMC) retain responsibility for adjudication hearings but where the panels are drawn exclusively from a single, central pool, trained by CHRE and working to common rules, procedures and sanctions. This would deliver common high standards whilst preserving professional ownership.

14. Implementation will require both primary legislation and widespread consultation. In legal terms, any type of proceeding which could deprive a person of their livelihood needs to meet the tests in the Human Rights Act if it is to avoid successful challenge in the courts – in particular the test of being an “independent court”.

Appeal process

15. The final stage is the appeal process, with current arrangements involving a right of appeal to the High Court for the registrant and powers for CHRE to seek to have “unduly lenient” outcomes reviewed also by the High Court. If full separation is achieved between prosecution and adjudication, it may be possible for CHRE’s current role to pass back to the regulator.

Chapter 5: Regulating staff with lower levels of qualification

Summary:

A successful outcome to the Scottish pilot of employer-led regulation of support workers could lead to the adoption of a UK-wide employer-led approach to the regulation of this group of workers.

1. In England, there have been calls for consideration of regulation of support workers since 1999, on the basis that as roles develop, much of the work formerly done by registered professionals is now done by healthcare assistants and other support staff. Assistant practitioners (as described in the draft Career Framework for the NHS in England) in particular are being developed to free up more professional staff to take on more advanced roles. A review of whether professional registration is set at the right level to ensure public protection was heralded by the commitment in the English NHS Plan 2000 to consider proposals for the effective regulation of support workers.
2. Similar considerations apply to Wales and Scotland. In N Ireland, in contrast to the remainder of the UK, healthcare and social care operational responsibilities are carried out by unitary organisations. This has led to a blurring of boundaries for support staff and the present position is that persons “engaged in the provision of personal care for any person” are eligible to be registered with the Northern Ireland Social Care Council (NISCC) as social care workers. The Department in Northern Ireland has the power under Section 8 of the HPSS Act (NI) 2001, to “by regulations make provision for prohibiting persons from working in such positions as may be prescribed unless they are registered in, or in a particular part of, a relevant register” i.e. in Northern Ireland the NISCC Register.
3. The Department of Health carried out a public consultation on behalf of England, Wales and Northern Ireland, with a parallel consultation by the Scottish Executive Health Department in 2004. The responses to the DH led consultation indicate that
 - The majority of respondents were in favour of statutory regulation for some, but not necessarily all, support staff, but a minority felt this was unnecessary.
 - There was a general feeling that there is a need for more debate and a fuller consideration of the implications and options.

- There was roughly a 70%/30% split in favour of the Health Professions Council (HPC) regulating support workers, with many nurses and professional bodies preferring NMC to regulate Healthcare Assistants (HCAs)/nursing assistants; also professional bodies wanted to regulate those who support their own professions.
 - There was thought to be a need for more work on collaborative regulation. Professional bodies and staff wish to share development of standards for their support staff with input from the staff involved. There was no clear consensus on who should be involved in setting standards and who should own them.
 - Suggestions for regulating new groups included a wide range of support workers at different levels on the career framework and very different stages of readiness in terms of nationally-recognised competences and training:
 - assistant practitioners;
 - HCAs/care assistants;
 - therapy assistants;
 - scientific support staff;
 - ambulance technicians.
 - Some suggested that porters, administrative and clerical staff and educational assistants should also be regulated.
 - Others suggested that statutory regulation was not the answer for support staff since it could be burdensome and reduce recruitment if registration dependent on qualification was a pre-requisite for employment.
4. Responses to the parallel consultation in Scotland similarly supported the introduction of statutory regulation. Respondents also felt that, to avoid multiple registration and to facilitate transferability of staff between the 4 UK countries, it would make sense for existing regulators to work together to develop core/common standards, with some discipline specific standards. 64% of respondents felt that Scotland should follow any decision that might be taken in England.



5. There is a strong overall case for extending regulation to at least some support workers. However, it does seem sensible to first study the results of the Scottish pilot as there is an urgent need for factual information about the advantages and disadvantages of an actual scheme of regulation as opposed to consideration in the abstract. To address this, the Scottish Executive has launched a pilot scheme. Each of the other UK countries has given this pilot their support.
6. The Scottish pilot tests an employer-led approach, backed by a non-statutory register. A successful pilot would establish this as a model for the way forward across the UK, and in particular would provide the opportunity for further consideration of key elements, including:
 - Standard setting for admission to the register.
 - Using National Occupational Standards to provide descriptors for induction and competence requirements.
 - Whether different approaches might be appropriate for different groups.
 - Use of risk assessment to identify those groups to be given priority for inclusion.
 - Use of Agenda for Change levels (e.g. 3 and 4) as criteria for point of entry.
 - The balance between individual and employer responsibilities in relation to keeping track of training and similar updating requirements.
 - Effective audit and monitoring of the employer-led activity.
 - Logistic issues such as which independent body should keep the register, keeping the register up-to-date, and involvement of informal/non-NHS employers.
 - Legal issues about the interface between employers and the independent registration body.
 - Who should fund such a scheme – one possibility might be a combination of an annual fee set at a low level to be contributed by the staff themselves and a substantial element of subsidy by employers.

This might effectively balance the need for individual commitment with the need to minimise additional burdens. The additional burden for employers might well be offset by the increased value and commitment associated with the introduction of regulation.

7. The pilot is being taken forward under the aegis of a 4-country Steering Group which met for the first time in Edinburgh on 19 October 2005. The pilot is due to report at the end of 2006 and will enable decisions to be made in 2007 about future arrangements for the regulation of healthcare support staff.

Chapter 6: Regulating new professional roles

Summary:

- The new roles using the working titles¹ of Anaesthesia Practitioner, Emergency Care Practitioner, Endoscopy Practitioner, Medical Care Practitioner and Surgical Care Practitioner need statutory regulation, if healthcare providers agree they are fit for purpose.
 - Work remains to be done about the exact form this should take: whether they should be regulated as one group with specialisms, or as up to five separate groups.
 - One or more existing regulators will become the “lead regulator” for new groups. The lead regulator will set the standards applying to everyone registering as a member of the new group. Where someone joins the new group from an existing profession, they can remain registered with their existing regulator
1. Many healthcare professionals expand their practice to take on duties previously done by others, or to extend their breadth of skills and knowledge within traditional roles. This extended scope of practice does not necessarily require further regulation in its own right.
 2. Beyond such extensions of an existing scope of practice, however, sometimes new roles are developed whose content goes well beyond that of the existing professions from which they spring. Examples include those being recognised by England and Wales’ New Ways of Working project, which has identified a number of new roles, in particular:
 - **Surgical Care Practitioners (SCPs)**, who assess and treat patients not only pre and post operatively but also perform elements of or the complete surgical procedure. Most current trainees are former ODPs and nurses.
 - **Anaesthesia Practitioners (APs)**, whose role includes maintaining anaesthesia as well as other duties previously performed by medically qualified anaesthetic staff. Most current trainees are former ODPs and nurses. This role is currently being piloted in N Ireland and England.
 - **Medical Care Practitioners (MCPs)**, who assess, make high-level differential diagnosis, treat and provide follow up care holistically across the patient’s overall physical and psychological condition, in primary care or acute

¹ All these are working titles only. The move to statutory regulation would include consultation on the titles to be protected.

medical settings. Current trainees are from a wide variety of backgrounds: medically trained people from overseas (including refugee doctors unable to register with the GMC), graduates in science or psychology, nurses, physiotherapists and other Allied Health Professionals (AHPs).

- **Emergency Care Practitioners (ECPs)**, who undertake independent “see, treat, discharge or referral” practices. Most ECPs come from practice as paramedics or nurses.
 - **Endoscopy Practitioners (EPs)**, who perform complex endoscopy procedures. EPs come from a variety of healthcare backgrounds . They are not necessarily the same as nurse endoscopists, who are working in Northern Ireland, Scotland and England.
3. Since the path by which these roles have developed has normally involved people in an existing profession pioneering the new role, the decision about where to draw the line between a genuinely new role and the extension of an existing one is quite complex. More work is needed on this, but one significant criterion is that direct entry to the new role is possible, bypassing membership of any existing healthcare profession. At this point, if no earlier, patient protection requires that people practising these high-level competences, comparable with those of existing regulated professions, should themselves be regulated.
 4. The five roles set out above urgently need statutory regulation as new roles. Work remains to be done about the exact form this should take – whether they should be regulated as separate groups or as one generic group, and which existing regulatory body should take responsibility for them. This will be taken forward as an early priority, subject to further but rapid consideration of whether a more generic approach might be effective.
 5. The question also arises whether a person who moves into one of these five groups from an existing regulated profession should have to either give up their existing registration or hold dual registration (which would be costly and bureaucratic). Recognising that many professionals feel a degree of loyalty to the specific group in which they were first registered, a system of “distributed regulation” should be established under which they could remain with their existing regulator.
 6. Under this approach, one of the existing regulators would become the “lead regulator” for each new group. The lead regulator would set the standards applying to everyone registering as a member of the new group. Where



someone joined the new group from an existing profession, for example nursing, they could remain registered with their existing regulator, in this case the NMC, once they had been accepted by the lead regulator as meeting their standards.

7. While the new roles are very new, a pioneer group have developed them and would be among the first to register in them. From a patient safety point of view there is nothing to be gained by requiring this group to undertake formal training, once it exists, if it replicates training they have already received while developing the role. But there is a need for individual practitioners to demonstrate their fitness to practise against the standards of proficiency based on the competences developed once the role itself has been established and the decision taken to regulate it in its own right. So all those who wish to practise in those roles will need to demonstrate that they are fit to practise as such to achieve registration in the new role. This is known as 'grandparenting'.
8. For the future, there will need to be a set of criteria about the tests a new role must pass for statutory regulation to be considered necessary. The Health Professions Council's set of tests for aspirant professions is:
 - Discrete area of activity
 - Defined body of knowledge
 - Evidence based practice
 - One professional body representing most practitioners
 - Voluntary register
 - Defined entry routes to training
 - Independently assessed qualifications
 - Code of conduct applied to voluntary registrants
 - Disciplinary processes applied to voluntary registrants
 - Commitment to Continuing Professional Development.
9. A set of tests will be developed on these lines to apply to future roles. The different UK Health Departments see considerable value in agreeing a single approach to the regulation of these emerging roles, and will work to do so in the course of 2006, including, as a priority, considering whether there may be any value in developing a more generic approach – although this should not be allowed to delay seriously the development and regulation of the distinct roles identified earlier in paragraph 2.

Chapter 7: The role, structure, functions, governance and numbers of regulatory bodies

Summary:

- All regulators have the same role of protecting the public.
 - There are substantial areas in which common standards would be desirable – in particular most aspects of conduct. The regulators and CHRE should work to introduce common standards in all those areas where this would benefit patient safety.
 - Some or all of the elected professional members of Councils should be replaced by appointed professional members.
 - Comments are invited on the future balance of Councils between professional and lay members, with the possibility of either a professional majority of one, a lay majority of one or no change.
 - Changes are needed to the membership of CHRE's Council.
 - Any new profession coming into statutory regulation should be regulated by one of the existing regulatory bodies, most likely the HPC.
 - The PSNI should remain as an independent body for the time being but with shared functions with the RPSGB. In the longer term, however, the two societies should amalgamate into a single UK body, following the passage of the necessary primary legislation. At the same time any necessary changes can be made to clarify the separation of the RPSGB's regulatory and professional lead functions.
 - We will keep under review the question of whether harmonisation delivers the appropriate benefits or whether there should be further progress towards fewer regulatory bodies. We will review the position after five years, in 2011.
1. This chapter considers these issues in the light of the discussion in preceding chapters about how regulation needs to develop to protect the public better. Public protection, rather than any preconceived view about the "right" answer, has to be the starting point.
 2. The role of the regulatory system, and of regulatory bodies within it, should be to ensure patient safety, although there are other important if subsidiary objectives such as to maintain public confidence and trust. This does not



involve any significant change to the way regulators currently see their roles or the way they are set out in legislation.

3. Four regulators currently have a role outside the scope of regulation. The RPSGB, the PSNI, the General Chiropractic Council and the General Osteopathic Council are each charged in law or in a Charter with promoting their profession, in subtly different ways. While there is no suggestion that they are expected to put the good of the profession before that of the public, these words have caused uncertainty and dispute at times. Although the roles of professional leadership and promoting the profession, which have to be exercised for the public benefit, do indeed benefit the public, there is a tension between their focus inwards on the professions' interests and the need for the regulator to be seen to be free from such influences. The implementation of changes following this review will provide opportunities to bring the regulation of these professions into line with the majority.
4. The main functions of a regulatory body are:
 - setting and promoting standards for admission to the register and retention on the register;
 - keeping a register of those who meet those standards (including in future checking that registrants continue to meet the standards), and
 - administering procedures (including making rules) for dealing with cases where a registrant's right to remain on the register is called into question.
5. Chapter 5 discussed the possibility that the adjudication function contained in the last of these should move to an independent body. That would include the making of Rules affecting adjudication. It would leave the investigation of concerns and the decision about which concerns were serious enough to put before the adjudicator with the regulatory body, as now.
6. The other functions listed in paragraph 4 remain the core purpose of a regulatory body: *to produce standards and maintain a register of those who meet them*. These functions should remain with regulators. Some of the purely administrative functions involved in keeping a register up to date could perhaps be done more effectively if they were shared.
7. While the setting of standards is the heart of each regulator's activity, there are substantial areas in which common standards would be desirable – in particular

most aspects of conduct. The more difficult task of identifying common educational standards in areas such as the knowledge needed to underpin safe prescribing should not be ducked either. The regulators and CHRE should work to introduce common standards in all those areas where this would benefit patient safety.

8. Turning to the subject of governance, public safety has to be reconciled with a sense of professional ownership. There is no evidence that professional members of Councils and committees in general see themselves as there to serve “selfish” interests of their profession. There are valid concerns however. The public perceives regulators as dominated by members of the profession they regulate, and the fact of election plus the possibility of partiality strengthens this unhelpful perception.
9. It is therefore desirable to replace some or all of the elected members by appointed professional ones. A clear person specification is required, identifying desirable qualities and possibly also excluding individuals with a perceived conflict of interests (such as, arguably, those holding national office in representative bodies for the profession or professional defence organisations). Professional majorities on each regulatory body could remain, but they should in future be made up differently.
10. It is worth considering the balance in numbers between the professional members of Council and the rest. Comments are invited on three options: keeping the present distribution (a small, varying, professional majority), aligning all Councils to have a professional majority of one, or moving to the General Social Care Council model where there is a small lay majority. The practical impact of change would not be great since it is unusual for Councils to divide along such lines, but it would strengthen the public and patient voice, and send a strong message to the public that regulation was a partnership between profession and public. And finally, as Dame Janet Smith made clear, too ready an understanding of the realities and pressures that attend professional practice may itself generate a blindness to the interests of others – the patients and wider public.
11. A related change is needed to the constitution of the Council for Healthcare Regulatory Excellence (CHRE). The membership of its Council since establishment in 2002 has consisted of the nine Presidents of regulatory bodies and ten lay members. This was a necessary and successful approach while the



new body was finding its feet and winning the respect of the professional world. In the long run, however, a large Council with such a substantial presence from the regulatory bodies themselves hampers CHRE's ability to act as freely as we would wish to promote more consistent professional regulation. Changes to the membership of the Council will be developed which will preserve its lay majority (and UK-wide makeup) while securing a professional voice through appointments against objective criteria. CHRE's close working relations with the regulators will in future need to be furthered by other kinds of contact rather than by Presidents sitting on its Council.

12. Finally turning to structure and numbers, this chapter concludes by examining whether there should be fewer regulatory bodies.
13. The greater consistency of approach produced by having fewer regulators would benefit public protection in a number of ways. While standards could still be tailored to different situations affecting different professions, as the HPC does, having simple generic standards about, for example, conduct would be easier to achieve. Having fewer regulators would make a more consistent approach to (for example) education easier, with common standards for areas like student conduct easier to achieve. Higher Education Institutions (HEIs) with programmes for more than one profession would cope more easily with the requirements of fewer regulators, making compliance more reliable.
14. Consistency in the handling of fitness to practise cases, for example in the standards of conduct required and the standard of proof applied, would encourage members of the public and employers to contact the regulator in the confidence that their complaint would be handled fairly. With fewer bodies to complain to, working out the right course to take would be simpler. Advice to bodies like Citizens Advice Bureaux would be simpler. Evidence we received from a number of patient and public groups made this point.
15. Against this, it can be argued that the existing diversity of regulators allows each one to understand its profession(s) better and tailor its work to areas of greatest importance, as well as drawing on particular expertise. There must be some force in this.

16. Some of the objections to a reduction in numbers are also based on patient protection. Structural change can be a distraction from other reforms which call for cultural change. This has to be a consideration taken seriously in any programme of change.
17. Another important note of caution is the need to maintain professional buy-in for the system of regulation. There could be a risk that the merger of existing regulators could alienate members of the affected professions. This is not automatically so and could be guarded against, in particular in the important area of standard-setting, where professional bodies would need to continue to feel that they were key players.
18. Risk is an area which needs close attention in any change proposals. Risks include the loss of knowledge and of key staff, delay and expense, and the failure of new systems to work as expected straight away. Options involving structural change clearly involve more of these risks than the other options. However there are also risks in preserving the status quo, for example that small regulators will not be able to deliver key functions to an adequate standard as the challenges increase. Risks of change can be managed by, for example, allowing long enough for changes to be properly planned and prepared, building on existing institutions and practices which work well, and careful communication.
19. A regulator like the Health Professions Council, dealing with a range of disparate professional groups, can deliver the functions which public protection requires. Professional bodies dedicated to providing leadership and developing the future scope of practice as the professions develop, which can then inform the regulators' standards-setting function, are also needed: the two work together.
20. It follows that any new profession coming into statutory regulation should be regulated by one of the existing regulatory bodies, probably the HPC. Some aspirant groups have argued that new bodies should be set up to regulate their professions. The preceding discussion has led to the rejection of that approach.



21. We considered carefully the arguments for mergers between any of the existing regulators. While the discussion above makes a reasonably good theoretical case for having fewer regulators, we have decided against this on practical grounds. The evidence available to us is that regulators today, including the smallest UK ones, are able to carry out their functions effectively.
22. In relation to the future of pharmacy regulation in Northern Ireland, the Department of Health, Social Services and Public Safety has recommended that the Pharmaceutical Society of Northern Ireland should remain as an independent body for the time being but with shared functions with the Royal Pharmaceutical Society of Great Britain. In the longer term however the two societies should amalgamate into a single UK body, recognising that this would require primary legislation.
23. For completeness, one other regulatory body needs to be mentioned. The government has already announced that the Hearing Aid Council will be wound up and its functions transferred to a new regulator for consumer protection of all kinds. The Department of Health is looking at how the regulation of hearing aid audiologists might best be delivered in future, perhaps within the HPC.
24. In the longer run, the question of whether there should be further progress towards fewer regulatory bodies will be kept under review – with the intention being to hold a formal review of the position after five years, in 2011. It may be that in practice the need for further structural change can be avoided by closer collaboration and harmonisation between all the remaining regulatory bodies.

Chapter 8: Connections with CMO's report *Good doctors, safer patients*

1. The review of non-medical regulation was carried out in parallel with CMO's review of medical revalidation and related subjects, *Good doctors, safer patients*, which is being published on the same day. This document touches on a number of the same subjects, and so the discussion here has made the necessary connections at key points, for example in discussing revalidation in chapter 3 and fitness to practise in chapter 4.
2. There were also, however, some subjects in *Good doctors, safer patients* which do not find a parallel elsewhere in this document. This chapter therefore runs through those subjects and relates them to non-medical professional regulation to demonstrate how our thinking links up.
3. One of the themes of *Good doctors, safer patients* is managing information on doctors to help avoid unsafe practice. That document suggests, for example, that in primary care a modernised GMC register would do away with the need for Primary Care Trusts (PCTs) to hold Performers Lists of GPs, though PCTs would still play a key role. We would note here that PCTs also make arrangements for primary care services with dentists, pharmacists and optometrists, all of which have PCT Performers List arrangements. In the light of responses we receive to consultation, we would want to take a common approach to the different Performers Lists.
4. *Good doctors, safer patients* also talked about the confidentiality of data held for these purposes. While recognising calls for all data to be disclosable, that document concluded that patients would be better protected if "softer" information, indicating possible rather than clear concerns, was confidential to the regulator and only disclosed under certain conditions to for example an employer, rather than the public. This would make it more likely that such information would be handed over to regulators in the first place. These principles are equally relevant to the other health professions.
5. Incentives for safer practise were another area in which CMO's recommendations can apply more widely. We are in the process of making professional indemnity cover a condition of registration for all professions. CMO felt that the providers of indemnity services might be persuaded to offer lower premiums to those who could demonstrate a record of safer practice. We would hope this would apply equally to the other health professions who obtain cover from these organisations.



6. The proposal in *Good doctors, safer patients* about approaching the European authorities over language testing for doctors coming onto the UK register from Europe also has wider implications. We expect to deal with the issue of language testing in a consistent way across all the health professions.
7. *Good doctors, safer patients* also proposes the registration by the GMC of undergraduate medical students. Registration of students has been recently introduced for social workers and for opticians. We need to understand what the regulatory costs and benefits of spreading it wider would be and intend to study these to reach a decision about whether it should be extended to other groups in addition to medical students. Comments about any of these issues would be welcomed during the consultation period.
8. The recommendation of an NHS addiction treatment service for doctors raises similar issues for other healthcare workers. However, we would like to understand the costs and benefits of extending such a service beyond doctors and will study this, in the light of responses to the consultation. Similarly, *Good doctors, safer patients* proposes that locum agencies should be registered with the Healthcare Commission. The regulatory impact, both costs and benefits, of extending this to agencies supplying non-medical locum staff needs to be considered.
9. Finally, *Good doctors, safer patients* addresses the question of the standard of proof in fitness to practise cases, and concludes that the standard should be the civil law one of proof “on the balance of probabilities”. This is already the standard used at the Health Professions Council and it is our view that this standard should apply to all professional jurisdictions. This matches one of Dame Janet Smith’s recommendations (for doctors) in the Fifth Report of the Shipman Inquiry.

Chapter 9: Action Plan

1. This report and *Good doctors, safer patients* establish the direction of travel. Following consultation and further work on the practicalities of implementation, more operational details will be made available, following discussion with those most affected.
2. Many of these decisions can be implemented without legislation. Some elements of this programme can be achieved in secondary legislation, for example some changes in the membership of the Councils of the different regulatory bodies. This can be secured in an Order under section 60 of the Health Act, 1999. Following a review of the process of managing s.60 orders which was completed in January last year, changes have been made which will ensure these Orders are managed more effectively in future, without undermining the effectiveness of public consultation and Parliamentary scrutiny. This review also introduced the concept of Orders which introduced a similar change across all the regulators at the same time – a “portmanteau” Order. We plan to bring such an Order forward on this subject covering all the different regulators. It is a requirement of such Orders that the government consults on their contents before laying them before Parliament for approval.
3. Any of the options for improving adjudication would require primary legislation. Following consultation, provisions for this will be included in a future Bill to be laid before Parliament when the government's legislative programme allows.
4. Existing commitments to legislate by section 60 Order for the modernisation of pharmacy regulation, medical registration, the regulation of applied psychology and healthcare sciences will be honoured.
5. This substantial programme of legislation will need to be matched by redoubled efforts from the world of professional regulation, and from employers, to secure a more integrated and effective approach to regulation.
6. Progress will be reviewed in 2011 and any necessary decisions about future directions will be taken at that point.

Appendix 1: Membership of the Advisory Group

Member	Organisation
Andrew Foster	Director of Workforce
Chris Beasley	Chief Nursing Officer
Kay East	Chief Health Professions Officer
Sue Hill	Chief Scientific Officer
Raman Bedi	Chief Dental Officer
Jeannette Howe	Acting Chief Pharmaceutical Officer
Jane Wesson	Chairman, CHRE
Sandy Forrest	Director, CHRE
Steve Barnett	Director, NHS Employers
Alastair Henderson	Deputy Director, NHS Employers
Sarah Thewlis	Chief Executive, NMC
Marc Seale	Chief Executive, HPC
Hew Mathewson	President, GDC
Ann Lewis	Registrar, RPSGB
Nic Greenfield	Deputy Director – Workforce, DH
Steve Catling	Head of Professional Standards, DH
Harry Cayton	National Director for Patients and the Public, DH
Norman Morrow	DHSSPS, Northern Ireland
Paul Martin	Chief Nursing Officer, Scottish Executive
Stephen Redmond	HR Director, Wales
John Wilkinson	Principal Research Officer, DH

Appendix 2: Definitions adopted by the Advisory Group to the Review

This note reflects our initial analysis and ideas as discussed and amended by the Group and has also been amended to reflect comments and the outcome of discussions elsewhere.

Regulation

Regulation is the set of systems and activities intended to ensure that healthcare practitioners have the necessary knowledge, skills, attitudes and behaviours to provide healthcare safely.

This encompasses activity undertaken by individual professionals, teams, employers, regulatory bodies and other organisations such as Higher Education Institutions.

The core activities of regulation are therefore listed in the Health Act (1999) as:

- (a) keeping the register of members admitted to practice,
- (b) determining standards of education and training for admission to practice,
- (c) giving advice about standards of conduct and performance,
- (d) administering procedures (including making rules) relating to misconduct, unfitness to practise and similar matters.

Revalidation

Revalidation is the process by which a regulated professional periodically has to demonstrate that he or she remains fit to practise

- in terms of competence, or perhaps better, performance (see below), health, and conduct/character.

Appraisal

Appraisal is the process by which others (whether peers, superiors or others) assist a person to review their performance and draw lessons from it.

Competence

Competence is built up from knowledge (for example facts about physiology) and skills (for example inserting an intravenous line safely and effectively). Modern HR practice breaks the requirements for any job down into several individual competences. An example of one would be history taking and consultation skills. In a wider sense, “competence” to carry out an entire role consists of having all the individual competences required, plus the ability to use judgement at a higher level (for example by knowing when to use which competence and when it is clinically right to depart from a standard clinical approach).

The agreed working definition of “competence” from the Scottish OPRS Committee is the “consistent integration of skills, knowledge, attitudes, values and abilities that underpin safe and effective performance in a professional or occupational role.”

Competence is a practitioner’s current ability to practise an entire role, combining individual competences and the use of wider judgement.

Performance

There is an important difference between knowing what to do (competence) and actually doing it (performance). A **competent** radiographer knows how to use X-rays safely, but might sometimes fail to do so: one who **performs** adequately is a radiographer who always works in a safe way. Revalidation should be much more relevant to patient safety if it can test performance rather than competence.

Performance is the manner in which a practitioner has carried out a particular task or function. This is the observable part of competence.

Character and Conduct

Character is an elusive concept and our focus would better be directed towards conduct and, where possible, to the attitudes which direct it. The ‘moral strength’ to know what is right is what is important and is a feature of self-regulation. Irrespective of professional status this ‘quality’ should be expected/articulated.

Character is the combination of personal qualities which are relevant to a person's fitness to practise.

Conduct is that part of a person's behaviour which is relevant to his fitness to practise.

Appendix 3

Initial Regulatory Impact Assessment

The regulation of the non-medical healthcare professions

Contents:

1. Introduction
2. Purpose of RIA
3. Consultation
4. Options
5. Provisional costings of proposals

Annexes

- A. Governance and accountability
- B. Investigations and creation of an adjudication tribunal
- C. Revalidation and appraisal
- D. Regulation of new professional roles
- E. Options for merging regulatory bodies

Initial Regulatory Impact Assessment

The regulation of the non-medical healthcare professions

1. Introduction

1.1 This Initial Regulatory Impact Assessment provides the Government's early assessment of the likely impact of the major recommendations in Government proposals to strengthen the system of non-medical regulation as set out in ***The regulation of the non-medical healthcare professions*** published on 14th July 2006. The costs set out in this document are our preliminary estimates and will need to be refined as we move to implementation.

1.2 The programme of work to implement this report will be co-ordinated with work to implement the recommendations of Dame Janet Smith's report on Shipman and CMO's report *Good doctors, safer patients*, insofar as they are accepted by Ministers.

2. Purpose and intended effect

Objective:

2.1 A safer NHS through safer healthcare professionals such as nurses and pharmacists:

- Promoting and assuring good professional practice and protecting patients from bad practice.
- Rebuilding of public confidence in the regulatory institutions.
- Closing the gap between the regulatory responsibilities of the professions and healthcare organisations.

2.2 We aim to do this in a way which:

- i assures patients and carers that their complaints are listened to and taken seriously
- ii recognises and celebrates the high standards of service delivered by the vast majority of healthcare professionals
- iii supports learning and continuous improvement in all services provided to NHS patients.

Background:

2.3 The vast majority of health professionals practise to a high quality but there is a small minority whose standard is not acceptable whether through inadequate training, insufficient support, ill health, lack of motivation or malice. Publication of *Supporting doctors, protecting patients* [1999] and the *NHS Plan* set in motion the reform process, but there is unfinished business.

Rationale for government intervention:

2.4 The vast majority of healthcare interventions are completed through the NHS. Unsatisfactory practice compromises patient safety. The professions have a duty to identify such practice and to remedy it. However, they cannot do this on their own.

2.5 The Department of Health is more than halfway through the implementation of the ten-year plan set out in *The NHS Plan: A plan for investment, a plan for reform*. During this time there has been a series of reports highlighting weaknesses in the system of professional regulation that has failed to prevent the Shipman murders and the unforgivable abuse of patients by other doctors².

2.6 The most recent reforms of professional regulation began in 2001 with the establishment of the Nursing and Midwifery Council and the Health Professions Council. Legislative change has been under way for the other professions, based on the same principles of patient protection and responsiveness to the public interest.

2.7 Shortly after publication of the Fifth Report of the Shipman Inquiry the then Secretary of State for Health announced that he had asked Professor Sir Liam Donaldson, the Chief Medical Officer (CMO), to carry out a review of some aspects of medical regulation and to give his personal advice to ministers on his

2 **Smith J.** *The Shipman Inquiry*. Chairman: Dame Janet Smith. (www.the-shipman-inquiry.org.uk) *Fifth Report; Safeguarding patients: lessons from the past – proposals for the future*. Cmnd 6394. The Stationery Office, London, 2004.

Pauffley A. *Independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling*. Chairman: Dame Anna Pauffley. Cmnd 6298. The Stationery Office, London, 2004.

Matthews S. *To investigate how the NHS handled allegations about the performance and conduct of Richard Neale*. Chairman: Her Honour Judge Matthews. Cmnd 6315. The Stationery Office, London, 2004.

Pleming N. *The Kerr/Haslam Inquiry: full report*. Chairman: Nigel Pleming QC. Cmnd 6640. Crown, London, 2005

conclusions. Subsequently, the government announced a parallel review of regulation of the non-medical professions to be carried out by Andrew Foster, Director of Human Resources of the Department of Health. This second review, which forms the subject of this document, was needed to ensure consistency across the regulation of all the different health professions, and to ensure that the developing system of regulation remained fit for purpose.

3. Consultation

3.1 Andrew Foster was supported by an advisory group which met 10 times during 2005 which included a few departmental but mostly non-departmental members. The review was also supported by a wider reference group of over 70 which included the main patient, employer and professional groups and all the regulatory bodies. This group commented on papers and met twice.

3.2 Officials from the devolved administrations played a full part in the advisory group.

3.3 MORI were commissioned to undertake a survey of public attitudes to the regulation of non-medical professionals and their revalidation. The review issued a Call for Ideas which generated 107 responses.

4. Options

4.1 Ministers have taken decisions about their preferred options, subject to consultation, in 5 key areas aimed at improving patient safety and an initial assessment of the likely regulatory impact of these is set out in the annexes:

- Governance & accountability annex A
- Investigations & creation of an adjudication tribunal annex B
- Revalidation & appraisal annex C
- Regulation of new professional roles annex D
- Options for merging regulatory bodies annex E

5. Summary of costs and benefits

Sectors and groups affected

5.1 The most direct impact will be on existing regulatory bodies. Created by statute, these need to be viewed in regulatory impact terms as part of the public sector. There will be some changes to their governance and they will need to carry out new regulatory tasks in relation to revalidation and (for some of them) the regulation of small new groups of staff.

5.2 There will also be an impact on individual health professionals. Over time they will be required to revalidate at intervals (probably five years) by producing evidence of their continuing fitness to practise. Where relevant, appraisal and assessment by their employer will be used for this. The currently small number of people in the new groups under consideration will come under statutory regulation. Nearly all are in fact members of existing regulated professions, but in future direct entry to the new groups will be possible.

5.3 Employers of healthcare professionals, whether in the public or private sectors, will be affected in the same ways. As revalidation is progressively introduced they will need to keep appropriate records to support it, so that they can be accepted as reliable partners in the revalidation process. Where they do not or cannot, their professional employees will need to make direct arrangements with the regulator to supply the necessary revalidation evidence.

5.4 The users of health services will be indirectly affected by experiencing more reliable services in which they can have greater confidence.

Benefits

5.5 Set out in the different options below.

Costs

5.6 Costs are very uncertain at this stage. However, our preliminary estimates of the cost of implementing the main recommendations in full are that introducing revalidation, the most expensive proposal here, could cost in the range of £35-50 million per year once fully operational. Changes to governance and accountability will produce small savings (less than £1 million per year). The costs or savings of changes to investigations will depend on the option chosen but will be in the low millions based on the cost of currently operating these systems. The cost of regulating new professional roles will fall on those who register and will depend on

their numbers. Based on the current costs of HPC registration, the cost per person would be £60 per year. There are no costs associated with our proposals on mergers (since they represent no change).

6. Equity and fairness

6.1 Any changes in the final action programme will impact equally on all healthcare providers, whether in the NHS or in the independent or voluntary sector, carrying out equivalent activities. It is our intention that any regulatory impact should be proportionate to risk; more robust precautions may therefore be needed for activities which are inherently more risky, eg administration of chemotherapy, or where practitioners are working in isolation rather than as members of clinical teams.

7. Small Firms Impact Test

A number of providers of healthcare services fall into the category of “small firms”, for instance independent community pharmacies. As already mentioned, we are consulting stakeholder organisations representing small firms. In the meanwhile our provisional view is that the action programme is unlikely to have a disproportionate impact on small firms.

8. Competition assessment

not needed at this stage

9. Enforcement, sanctions and monitoring

not needed at this stage

July 2006

Department of Health

Governance and accountability

annex A

Objective

- Increase the accountability of the different regulatory bodies
- Ensure that the members of their Councils are not beholden to any specific constituency and that they bring the appropriate mix of skills to the Council
- Address current negative perceptions of regulators in these respects through a demonstrable break with the past

Background

There is public and professional dissatisfaction with the different regulatory bodies, which are often perceived as either 'closed shops' or punitive and draconian organisations by these respective parties. Formally, the regulatory bodies are presently held to account by the Privy Council.

Rationale for Government Intervention

There have been changes to the governance of the regulators in recent years that include a higher proportion of lay members, while retaining a professional majority, and a distancing of Council members from the organisation's day-to-day operations (such as fitness to practise hearings). However, these changes do not yet appear to have improved the faith of the public or the profession in the organisation and the concept of Council members 'representing' specific constituencies lingers. Legislation will be required to bring about these changes.

Options – description

Option 1 (*do nothing*)

Changes to governance of the different bodies during 2001-2005 have led to the present position where there are small elected majorities of professionals on each council along with a lay member presence, appointed by the Appointments Commission. Stakeholders are unlikely to be convinced that sufficient progress has been made. Perceptions (as well as the reality) are important in generating and maintaining public and professional confidence.

Option 2 (*preferred*)

Establish new Councils appointed by a transparent independent process, such that Council members have the specific skills required to lead strategically and hold the executive to account. Ensure that effective and regular external scrutiny is paid to the performance of the regulators through Parliament.

Option 3 (*alternative*)

Abandon independent, professionally led regulation for a system operated solely by the State.

Option 4 (*alternative*)

Abandon the formal regulation of health professionals in favour of an approach whereby the desire of patients, and providers or commissioners of services to retain a professional's services would ultimately reflect the quality of that person's performance.

Options – costs and benefits

Option 1 (*do nothing*)

No direct additional financial cost compared to status quo. No benefits.

Option 2 (*preferred*)

There would be no increase in the cost of the regulators' governing bodies. Any increase in remuneration would likely be offset by a reduction in the size of the governing body and the saving in the costs of elections. A break with the past, increased transparency and intermittent external scrutiny would foster improved confidence amongst the public and a proportion of the professions.

Option 3 (*alternative*)

Costs would increase. State regulation would be unacceptable to the professions. A degree of professional 'ownership' of regulation can be regarded as a defining feature of professionalism and is essential to engagement.

Option 4 (*alternative*)

The costs to the NHS and wider society resulting from medical injury, disability, premature death and litigation would be very large. The safety of individual patients would suffer to a wholly unacceptable degree.

Objective

- Introduce a transparent and demonstrably independent adjudicatory body on fitness to practise issues

Background

In the past, each regulator has acted as lawmaker, investigator, assessor, formulator of charges, prosecutor, judge and jury in fitness to practise cases. There are difficulties inherent in this approach. The consistency of the decisions of regulators' panels has been a source of comment in the past. Recent changes to the composition of fitness to practise panels (removing Council members and replacing them with appointed panellists) offer only a partial solution.

Rationale for Government Intervention

A separate and specialised tribunal to undertake formal adjudication (in place of the regulator) will permit improved quality and consistency in decision making whilst also providing objective independence from both the regulator and the Government. Legislation will be required to bring about these changes.

Options – description

Option 1 (*do nothing*)

Continue with current system of panellists appointed by the regulator.

Option 2 (*alternative*)

Establish an independent tribunal before which the General Medical Council may prosecute registrants if necessary following investigation and assessment.

Appointed medical and lay panellists through a transparent and independent process. Legally qualified chairs. No change to the systems for other professions.

Option 3 (*alternative*)

A multi-professional independent tribunal to adjudicate on fitness to practise matters in all healthcare professions (so that for example, a nurse or pharmacist might sit on the panel in judgement on doctors and physiotherapists).

Option 4 (*alternative*)

Retain the existing structure of each regulator organising hearings. Replace the separate panels for each regulator with a single central group of panellists with

common training, standards, guidance on indicative sanctions and access to the same range of sanctions.

Options – costs and benefits

Option 1 (do nothing)

No direct additional financial cost compared to status quo. No benefits.

Option 2 (preferred)

Significant set-up and running costs estimated at £11 – 13 million per year³.

Increased consistency, legal quality and clarity in adjudication leading to a lower number of appeals and reduced legal activity and connected costs.

Option 3 (alternative)

Significant set-up and running costs. Economies of scale. Significant departure from concept of professionally led regulation. Likely to be unacceptable to medical profession.

Option 4 (alternative)

Modest set-up costs. Running costs long-term would be slightly less than current ones in view of economies of scale.

³ Figures derived from current GMC spending on 'adjudication': some of this expenditure may remain with the GMC (for example legal fees for 'prosecution').

Revalidation and appraisal

annex C

Objective

- Creation of a system that will provide objective and robust assurance that individual professionals remain fit to practise
- To standardise the content and enhance the value of workplace appraisal

Background

There is a growing consensus that professionals must intermittently prove that they are worthy to remain on the medical register. The General Medical Council produced a proposal for a system of regular revalidation for doctors but this was heavily criticised by Dame Janet Smith. She found it to be neither robust nor objective and suggested that it would provide little more than false reassurance to the public. A process of compulsory annual appraisal was introduced for career grade doctors in the NHS in the early 2000s, and for other professionals in the NHS as part of *Agenda for Change* in 2005. Whilst this process works well in some areas, it delivers little in others. There has been much debate as to whether appraisal is formative (developmental), summative (judgemental) or a combination of the two. The public believe that the performance of professionals is already assessed intermittently – it is not.

Rationale for Government Intervention

Dame Janet Smith's criticisms of revalidation as proposed were forceful and well-founded. Revalidation cannot proceed as then proposed. An alternative model of revalidation, providing objective assurance (generally after some form of validated assessment) must be developed. All professions providing patient care need a form of revalidation, and this should be delivered in a consistent way though this does not require that everyone's revalidation requires equal intensity or identical forms. A risk-based approach is called for in which the effort devoted to revalidation is proportionate to the implications for patient safety.

Options – description

Option 1 (*do nothing*)

Do not introduce any system of revalidation.

Option 2 (*preferred*)

Introduction of a risk-based spectrum of revalidation with more intensive focus where risk is greatest, for example with doctors. Revalidation for all registered professionals would occur every five years and involve satisfactory participation in annual NHS appraisal or equivalent (to be further developed and standardised), resolution of any issues known to the regulator and, where appropriate, participation in other standardised assessments. The proposals for recertifying specialist skills in *Good doctors, safer patients* could be extended to other high-risk professional groups where justified.

Option 3 (*alternative*)

Limit revalidation to the groups operating in the most high-risk areas, concentrating on staff with the most specialised skills.

Options – costs and benefits

Option 1 (*do nothing*)

No direct additional costs compared to status quo. No benefit.

Option 2 (*preferred*)

Significant costs estimated at up to £ 43 million per year depending on how many professionals needed to go through the more intensive forms of revalidation. Introduction of an inclusive system to provide meaningful assurance that every professional on the register is fit to practise in the role for which they are registered, introducing a uniform and explicit link between proven competence and ongoing permission to practise (for the first time in any major jurisdiction).

Option 3 (*alternative*)

Significant but lower costs than option 2. Assurance about safety would be targeted on the groups whose practice contained the highest inherent danger for patients.

Regulation of new professional roles

annex D

Objective

- To regulate clinical professionals performing new roles as effectively as those in existing roles for the protection of patients

Background

The development of new ways to deliver health services is creating new roles such as surgical care practitioners and emergency care practitioners, who may work at a similar or higher level as people in existing regulated roles such as nurses and physiotherapists. As training for these new roles is developed and direct entry to them is possible, bypassing membership of any existing healthcare profession, an approach to regulating them becomes more urgent.

Rationale for Government Intervention

Patients and those who employ staff in such new roles want the reassurance that an individual providing treatment is safe to do so.

Options – description

Option 1 (*do nothing*)

People moving from an existing profession into a new role would continue to be regulated by their existing regulator, but new entrants would not be regulated at all and their employer would have to take on the whole responsibility for verifying that they could practise safely.

Option 2 (*preferred*)

Extend the responsibilities of one or more existing regulatory bodies to cover genuinely new roles (rather than extensions of existing ones). These would include some or all of surgical care practitioner, medical care practitioner, anaesthesia practitioner, emergency care practitioner and endoscopy practitioner. People practising in these roles would need to register (though if already registered with a regulator, they could keep that registration rather than move to a different body once they had been accepted by the lead regulator as meeting their standards.).

Option 3 (*alternative*)

Set up a new regulatory body as and when required for new roles.

Options – costs and benefits

Option 1 (do nothing)

No costs. No benefits compared to existing position. As new groups of professionals came into being they would be unregulated although doing work at the same level as regulated groups. Unacceptable risk to patients.

Option 2 (preferred)

Costs would be the marginal cost of registering each new professional with an existing body, for example in the case of the Health Professions Council £60 per year or in the case of the Nursing and Midwifery Council £43 per year. Professionals pay their own registration costs so these costs fall on individuals. They are normally deductible against tax so the cost to the individual is reduced by 22%, this sum representing a loss to the Government. The benefit would be the protection of patients to the same standard whether their treatment was provided by someone in an established profession or in a comparable new professional role.

Option 3 (alternative)

Setting up new regulatory bodies is expensive, particularly as they need to accumulate the funds necessary to conduct legal proceedings if their decisions on fitness to practise are challenged. Set-up costs for even the smallest regulator would exceed £1 million. As new groups are building up their numbers slowly it is likely that the regulators' costs would have to be covered by a small group of registrants for some time, resulting in higher fees.

Options for merging regulatory bodies

annex E

Objective

- To secure the right organisational structure for ensuring that health professionals are effectively regulated to safeguard patients.

Background

At present, in addition to the GMC for doctors, health professionals are regulated by one of the following seven bodies: General Dental Council, General Optical Council, General Chiropractic Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Royal Pharmaceutical Society of Great Britain.

Rationale for Government Intervention

The terms of reference of the review of non-medical professional regulation required it to examine how patients could best be protected, and in the light of that to make any necessary recommendations about the numbers of regulators.

Options – description

Option 1 (*do nothing – the preferred option*)

No change in the number of statutory regulators in existence. Where new groups need statutory regulation, they would be added to the responsibilities of one of the existing regulators.

Option 2 (*alternative*)

Mergers between some of the existing regulators to produce larger statutory bodies.

Option 3 (*alternative*)

No change at present but create new bodies in future for the regulation of new groups.

Options – costs and benefits

Option 1 (*do nothing – the preferred option*)

No costs. Existing regulators carry out their statutory tasks effectively.

Option 2 (*alternative*)

Mergers which combined some of the smallest regulators with larger ones would

produce economies of scale. The smallest regulators currently have the highest registration fees and the largest ones charge least. However, these savings to individual registrants could be more than outweighed by loss of effectiveness if for example mergers meant that the regulation system could no longer supervise professional education effectively for all groups. There would also be risks from loss of professional support and engagement with statutory regulation.

Option 3 (*alternative*)

To create further public bodies in the future would increase administrative costs, which are substantial in this sector because of the need to be prepared to defend fitness to practise decisions against legal challenge. The benefit of creating further bodies, that it might increase the engagement of new professions with the regulation system, is hard to quantify and does not in the government's view outweigh the costs.



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Produced by COI for the Department of Health
273520 1p 1.5k Jul 06 (CWP)

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