Dear Colleague

Regulation of Healthcare Support Staff in England and Wales Consultation Document

I am writing to invite your comments on the proposals for extending regulation to a wider range of healthcare support workers as set out in the enclosed document.

In the NHS Plan the Government undertook to consult on extending regulation to a wider range of NHS staff in order to improve public protection. This commitment recognised that it is no longer adequate for regulation to be limited to professional groups such as doctors, nurses and osteopaths. Support staff are increasingly working as part of a wider healthcare team to provide efficient and high quality care and it is important that proper arrangements are put in place to regulate the practice of staff who are responsible for the provision of direct care to patients. As set out in this document the Government considers that the public would benefit from Health Care Assistants, Therapy Assistants, all sectors of the Healthcare Scientist workforce, Assistant Practitioners and others working at a similar level in healthcare being subject to statutory regulation.

The proposals outlined in this document will have a significant impact on the provision and quality of healthcare in England and Wales. We are committed to carrying out a comprehensive consultation exercise to inform decisions about the way forward for the future regulation of this group and to encourage debate. To this end we are seeking the views of support workers, their colleagues within the healthcare team, healthcare employers, existing regulatory bodies, the public and patients, trade unions, professional bodies and any other interested groups.

Please take the opportunity to read this consultation document and provide us with your comments and views on the important proposals outlined in it, which should be sent to Patrick Isaac, Education, Training & Development, Welsh Assembly Government, Cathays Park, Cardiff. CF10 3NQ or e-mailed to: patrick.isaac@wales.gsi.gov.uk by 2nd July 2004.

Yours sincerely

STEPHEN REDMOND
HR Director
NHS Wales Department
Regulation of Health Care Staff in England and Wales

A Consultation Document
Regulation of Health Care Staff in England and Wales

A Consultation Document
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This Government is committed to increasing public protection and improving quality in health care services. As part of this we promised in the NHS Plan to consult on proposals to extend regulation to support workers. We did this for a number of reasons.

First, increasingly a wider range of staff are involved in treating patients, taking on roles which were formerly the responsibility of professional staff and freeing them to concentrate on work that requires their skills. It is vital that we have proper arrangements in place to reassure patients that they are being treated by staff with appropriate skills.

Second, we need to ensure that arrangements are in place that require staff treating patients to meet standards of practice, conduct and training and to deal with those who do not meet the standards.

Thirdly, we need to reassure professional staff that all health care staff whose work impacts on patients are subject to proper regulatory arrangements.

This consultation document sets out our proposals for extending regulation to those staff who have a direct impact on patients and have the potential to compromise public safety if their work or behaviour falls short of acceptable standards.

I believe that these proposals will improve the quality of patient care and will help to reassure patients about the skills and competence of staff who care for them.

I look forward to receiving comments on our proposals.
Introduction

1. This consultation document sets out the Government’s proposals for extending regulation to a wider range of healthcare staff, seeks views on them and invites further debate. It builds on the commitment set out in the NHS Plan to publish proposals for the effective regulation of support workers, reinforced in HR in the NHS Plan to give consideration to a range of regulatory systems for support workers involved in day-to-day contact with patients. The regulation of currently unregulated staff is a matter for the devolved administrations in Scotland and in due course, when devolved power is restored, Northern Ireland. Wales is jointly involved in this pre consultation whilst Scotland and Northern Ireland will be consulting separately on proposals for widening regulation at a later stage. In doing so all four countries recognise the desirability of adopting a common approach to regulation in order to ensure that staff moving within the UK are not subject to different regulatory requirements. This document sets out:

The reasons for extending regulation
The groups that might be covered by regulation
How regulation might be undertaken
A timetable for action.

What do we mean by regulation?

2. Regulation exists to ensure standards of practice and to protect the public as far as possible against the risk of poor practice by regulated practitioners. It works by setting agreed standards of practice and competence, by registering those who are competent to practice and (if statutory) restricting the use of specified titles to those who are registered; and by applying sanctions such as removing from the register any whose fitness to practise is impaired.

Why should regulation be extended?

3. The Government is committed to providing an effective system for the regulation of all healthcare staff whose work has a direct impact on clinical patient care in order to protect patients. Most healthcare professional staff are already regulated. These include doctors, dentists, nurses, pharmacists, midwives, allied health professions, some healthcare scientists, osteopaths and chiropractors. But healthcare demands are changing and so is the way in which we respond to them. As the Government continues to provide greater choice of healthcare to patients, services are increasingly designed around the needs of patients and clients, to ensure they can receive the care they need when they need it from a person with the appropriate skills. Professional staff are increasingly working as part of a wider healthcare team to provide quick and effective care to patients. And unregulated staff, such as healthcare assistants and other support staff, are extending their skills so that they can undertake work previously done by registered professionals in order to meet patient needs. This is particularly necessary as nurses and allied health professionals take on extended roles to help employers to meet the European Working Time Directive for doctors.
4. To support this the Department of Health has been developing its wider Human Resources strategy for the NHS. This includes widening access to flexible training and career development; changing the way in which staff work with new roles designed around patient centred services; successfully negotiating new pay arrangements (Agenda for Change) which reward developing skills and competencies; emphasising the importance of lifelong learning and professional development and developing the concept of a skills escalator to encourage staff to make maximum use of their potential. All these developments mean that a wider range of staff, with a diversity of qualifications and skills, are providing hands-on care to patients. This has profound implications for current regulatory arrangements. In particular:

• In order to ensure public protection it is no longer adequate for regulation to be limited to the current range of professional groups. Proper arrangements need to be put in place to regulate the practice of all staff who provide direct clinical care to patients;

• The increasing flexibility of the workforce means it is important to ensure that the regulatory system supports, rather than hinders, the changing nature of care.

5. Within the overall requirement to ensure patient protection there is a specific need to close obvious loopholes, which exist under the current regulatory frameworks. Staff who have been removed or suspended from an existing register could return to work in a healthcare setting as support staff and continue to put patients at risk because these staff are not currently regulated. The Department has already taken steps to reduce the risk of such re-employment in the NHS through requirements for Pre and Post appointment checks; the need to take up references; and systems of alert letters. These arrangements need to be strengthened to ensure that individuals who have been removed from registration by a regulatory body are prevented from taking up employment in a currently unregulated support role. It is important that the current gap in the regulatory system is filled in order to protect patients.

6. Furthermore support staff in Social Care are to be regulated by the General Social Care Council and it is wholly appropriate for the NHS to ensure similarly that its patients and service users are protected to the same standards, especially as many work in both health and social care settings.

7. To sum up, there are three main reasons for regulating healthcare support staff:

• To protect the public by requiring these staff to meet standards of practice, conduct and training and by dealing with those who do not meet the standards;

• To provide a regulated workforce of practitioners who can safely fill jobs vacated by professional practitioners as they take on extended medical roles, and who can build on this to go on to professional practice if they wish; and

• To plug gaps in the overall regulatory framework so that all staff in health and social care whose work could impact on patients or clients are subject to similar regulation.

The Government’s Proposals

Who should be regulated?

8. As indicated earlier, regulation has traditionally applied to a range of professional groups where regulatory bodies have defined the skills and knowledge required to practise within the profession; set standards of practice; and been empowered to take action against registrants who are alleged not to meet such standards.

9. However the continuing development of new roles, and the extension of the work performed by a range of healthcare staff such as healthcare assistants and therapy assistants means that increasingly staff providing care to patients are not covered by current regulatory arrangements. We believe it is important that the existing regulatory system should be extended to cover these staff in order to provide proper
assurance to patients about the skills and competence of those treating them. However in doing so it will be important to devise a regulatory structure which does not lock them into existing professional groupings but enables them to develop new career pathways.

10. The Government believes that regulation should be extended further. Some staff groups whom we believe should be subject to regulation in future, and who would benefit from more flexible regulatory arrangements are such as; healthcare assistants, therapy assistants, assistant practitioners, and others performing similar roles in routine care including:

• **Radiography Assistant Practitioners** who may work in radiotherapy or clinical imaging services – regulation of this group would enable assistant practitioners to work across the whole range of radiographic services. For example, they might initially be registered to provide radiotherapy but, as they develop skills in areas such as diagnostics, whilst they would be required to demonstrate further competence they would not necessarily be required to undertake additional registration;

• **Rehabilitation Therapy Assistants** who perform both nursing and therapeutic tasks such as physiotherapy or occupational therapy – these staff work in a multi-disciplinary environment and could not easily register through a single professional stream;

• **Pathology Assistant Practitioners** who carry out screening and testing of patient body samples to aid diagnosis and treatment – for example, medical laboratory assistants who undertake pathology related tasks such as simple blood tests and specimen preparation. Regulation of this group of individuals would further protect the public interest.

There are other support staff who come into contact with patients work in areas such as domestic, portering, administration and clerical work, which does not involve direct clinical care provision. Deficiencies in performance by these groups of staff may be more appropriately managed locally by the employer through local standards of conduct and performance, training and, in extreme cases, disciplinary procedures. Since regulation does impose cost and creates some barriers to employment for staff and some burden on employers, we do not believe these staff should be included within formal regulatory arrangements, and consider that we should look to employers’ own arrangements for tackling poor performance. Paragraph 13 sets out more fully our proposals on the groups of staff who should be subject to regulation and invites comments.

**What will be the benefits of extending regulation?**

11. It is essential that all staff groups who have direct contact with patients provide high quality care. Quality of care will be strengthened if healthcare assistants, assistant practitioners and other support staff are required to meet specified training and practice standards; to register with an appropriate regulatory body; and to be subject to action if their actions or behaviour fall short of accepted standards. Use of these standards will also give professional staff the confidence to delegate more skilled work to assistants and support staff, which can allow them to develop their role further. They will be able take on more work previously done by registered professionals and develop their own skills and competencies through the skills escalator, and through the new and more flexible NHS pay system contained in *Agenda for Change*.

12. As well as providing public protection, regulation also allows recognition of the enhanced role, skills and responsibilities that will be undertaken by assistants. Introducing regulation at an earlier stage in the career pathway will make it easier for assistants to move on to professional roles later if they wish. It will be an important element of the new regulatory arrangements to establish clear criteria, in terms of qualifications or experience, for admission to the register and to determine standards of practice.
Q1 How far should assistants and support staff be accountable for their own practice?

Q2 Should assistants and support staff set their own standards OR should those with overall responsibility for the work of these staff share in, or take, the lead in setting these standards?

What do we propose?

13. As indicated above we believe that regulatory arrangements should be extended to those staff who have a direct impact on patient clinical care and are not currently covered by existing regulatory arrangements. “Direct impact on patient clinical care” implies face-to-face provision of prevention, diagnosis, treatment and care sometimes involving the application of clinical judgement, and may also cover provision of technical analysis and scientific support involving patients’ body samples. It would cover the following proposed groups of staff:

• Health care assistants, assistant practitioners and those undertaking similar roles across a wide range of care settings;
• Therapy assistants;
• All sectors of the Healthcare Scientist workforce apart from the aspirant professions in paragraph 24.

Q3 Should regulatory arrangements be extended to healthcare assistants, therapy assistants, assistant practitioners, and others performing similar roles in routine care?
If not, which groups of staff should be included and on what criteria?

What form should regulation take?

14. There is a range of options for regulation:
statutory self-regulation;
statutory shared regulation;
voluntary regulation led by staff organisations; and
employer-led regulation linked to employment contracts.

15. We propose that the new groups to be regulated, subject to the outcome of this consultation, should be subject to statutory self-regulation ensuring that those registered have met the standards set to ensure safe and competent practice and thus public protection. Anyone who falsely claims to be registered commits an offence punishable by law. It ensures that there is an effective method in place for reviewing individuals on the register who are considered to be falling short of those standards and where necessary removing them from practice. Furthermore other approaches to regulation would not provide the comprehensive coverage, which we believe is necessary for patient safety and would not tackle the problem of regulatory gaps set out earlier.

Q4 Is statutory regulation appropriate or should other approaches be taken?
Who should regulate these groups?

16. The three main options that we have identified are:
   • the Health Professions Council which could oversee regulation for all healthcare support staff;
   • all existing regulators to take on the regulation of those staff who currently work with the professions they regulate. They would however need a wider legal remit than they currently have in order to regulate new groups. Also this option might presuppose that such staff’s roles will continue within the relatively narrow areas they occupy at present, with less facility to expand skills and competence to work in other areas of healthcare. The Government has already agreed that this is the best approach for professionals complementary to dentistry (currently dental therapists and dental hygienists), who have been regulated by the General Dental Council since 1986, and will be gaining a more integrated status within the GDC-regulated family in forthcoming legislation. We will be consulting later in 2004 on taking a similar approach to pharmacy technicians;
   • a mixture of the above, with some staff whose work is relatively specialised within a narrowly defined role being regulated by the regulator already covering that professional area, and others whose work may span several professional boundaries being regulated by an expanded Health Professions Council.

17. We have considered these options and believe that the most appropriate way forward would be to set up the regulation of these staff by means of a Statutory Committee within the Health Professions Council – the Health Occupations Committee.

18. This will be overseen by HPC and share the same registration and fitness to practise operations, thus minimising costs and registrant fees. The Health Occupations Committee would have its own registrant and lay members forming an additional part of the HPC’s Council, and its Chair would sit on the full Health Professions Council. The legislation governing the HPC would be amended to safeguard the position of these staff by making it a duty for HPC to consult the Health Occupations Committee when deciding matters of concern to them. It could have a parallel Education and Training committee of its own, with statutory links to that of HPC and to any other regulator which might be involved in contributing to practice and training standards for these staff. It would share HPC’s fitness to practise and registration machinery, Chief Executive and other staff.

19. In proposing this option we are determined to avoid unnecessary bureaucracy and to keep costs to a minimum. Our proposal to use the system already provided by HPC would avoid the need for a new separate regulator to set strategy and employ expensive senior executives. It would also save on premises, operational and training costs by sharing these with an existing group of registrants. This proposal should keep registration fees to a reasonable level, perhaps about £20-25 per registrant per year, an important issue for this workforce.

20. The Health Professions Council is, as part of its consultation on the implementation of the Health Professions Order, currently considering the criteria to be applied by the Council to extending its regulation to further groups. We welcome the thorough and positive approach HPC is taking in identifying the issues involved, including supervision, accountability and clinical autonomy as well as the regulation of emerging roles within new patterns of care delivery and ways of working which may call for a more adventurous approach.

Q5 Should the Health Professions Council (HPC) regulate those groups of assistants and support staff identified for statutory regulation? Are other options preferable?
Q6 If the HPC is the most appropriate body, should regulation be by way of a statutory Health Occupations Committee or would other options be preferable?

Q7 Would regulation of assistants and support staff by the bodies responsible for regulating those whom they support lead to other problems such as ‘second class’ workers?

Q8 Are there other options for the structure of statutory self regulation we should consider?

How can we regulate staff who move across traditional professional boundaries?

21. Regulation has to be relevant to the range of ways in which care is provided. It needs to support the development of flexible, multi-skilled staff working across traditional professional boundaries and across care settings. The development of a collaborative framework between regulators in both health and social care should be pursued in order to extend the protection of regulation without setting unnecessary barriers to staff movement. If regulation were by the HPC for example it would need to work with other regulators responsible for the professions with whom these staff work closely, perhaps through the use of shared or joint standards of competence.

22. Both the Nursing and Midwifery Council and the Health Professions Council have a statutory duty to co-operate with partners including other regulatory bodies, as does the General Social Care Council. This could facilitate the longer-term development of shared or mutually compatible standards for staff working in or moving between different settings; agreement between regulators about who regulates which group of practitioners; and shared registration information. In particular it could prevent the need for dual registration for staff moving between settings, and could help cross-boundary roles to develop with significant benefits for patients, staff and employers.

Q9 How can multi-disciplinary issues best be addressed? Should the regulators set common standards and/or recognise each other’s so that workers can move between different health and social care settings without the need for multiple registration? OR Could all assistants and support staff be regulated as a single group within a single framework including some shared standards and some discipline-specific standards?

Devolution

23. The regulation of currently unregulated staff is a matter for the devolved administrations in Scotland and in due course, when devolved power is restored, Northern Ireland. Wales is jointly involved in this pre consultation whilst Scotland and Northern Ireland will be consulting separately on proposals for widening regulation at a later stage. In doing so all four countries recognise the desirability of adopting a common approach to regulation in order to ensure that staff moving within the UK are not subject to different regulatory requirements.
Aspirant healthcare professions

24. Significant progress has been made towards extending statutory regulation to more professions who aspire to regulation. The current position is set out below.

• **Operating Department Practitioners and Applied Psychologists.** Both professions applied for regulation by the Health Professions Council in 2003;

• **Healthcare Scientists who have professional qualifications** including Clinical Perfusionists and Clinical Physiologists. These groups may begin to be ready for regulation by 2005 – if standards of training and practice have been sufficiently well developed by then;

• **Psychotherapists and other practitioners of “Talking Therapies”**. The Department of Health is continuing talks with the organisations concerned to try to agree a way forward for regulating these groups, but has accepted the need for regulation.

Timetable

25. Subject to final decisions to be taken in the light of this consultation, statutory regulation could be put in place for assistants and support staff by 2007 though it would take some time after that for all those staff groups agreed to achieve registration. A provisional timetable is:

• Consultation on proposals March to July 2004;

• Analysis and final decisions August 2004;

• Develop preparatory infrastructure necessary for statutory regulation:
  • standardised training or induction requirements as basis for registration, based on national occupational standards projects due to complete in 2004/5
  • accreditation and roll out of training if needed
  • identification and initial voluntary registration
  • code of conduct, performance and ethics – all complete by end 2005;

• Draft legislation, publish and consult from early 2006;

• Pass legislation by late 2006;

• Register and full regulatory system open by early 2007 (for a specified period until proposed staff groups achieve registration).

Conclusion

26. The Government is committed to increasing public protection and improving quality in health care settings. This document seeks views on the way in which regulation should apply to health care support staff. In particular your views on these proposals and the specific questions raised in the text, and summarised at Annex A, are sought by 2nd July 2004.
Annex A

Regulation of Health Care Staff in England

1. The Government is committed to providing an effective system for the regulation of all healthcare staff whose work has a direct impact on patient clinical care. “Direct impact on patient clinical care” implies face-to-face provision of prevention, diagnosis, treatment and care sometimes involving the application of clinical judgement, and may also cover provision of technical analysis and scientific support involving patients’ body samples.

2. The Government considers that the public would benefit from some form of regulation for the following proposed groups of staff:
   - Health care assistants, assistant practitioners, and those undertaking similar roles across a wide range of care settings;
   - Therapy assistants;
   - All sectors of the Healthcare Scientist workforce, apart from the aspirant professions in paragraph 24.

Below is a series of questions on which we would like your views. In the light of your responses the Government can decide what type of regulation should be developed, how the regulation should be achieved and how good inter-professional working can be facilitated.

Questions on which we are seeking your views:

Q1 How far should assistants and support staff be accountable for their own practice?

Q2 Should assistants and support staff set their own standards OR should those with overall responsibility for the work of these staff share in, or take, the lead in setting these standards?

Q3 Should regulatory arrangements be extended to healthcare assistants, therapy assistants, assistant practitioners, and others performing similar roles in routine care? If not, which staff should be included and on what criteria?

Q4 Is statutory regulation appropriate or should other approaches be taken?

Q5 Should the Health Professions Council (HPC) regulate those groups of assistants and support staff identified for statutory regulation? Are other options preferable?

Q6 If the HPC is the most appropriate body, should regulation be by way of a statutory Health Occupations Committee or would other options be preferable?

Q7 Would regulation of assistants and support staff by the bodies responsible for regulating those whom they support lead to other problems such as ‘second class’ workers?

Q8 Are there other options for the structure of statutory self regulation we should consider?

Q9 How can multi-disciplinary issues best be addressed? Should the regulators set common standards and/or recognise each other’s so that workers can move between different health and social care settings without the need for multiple registration? OR Could all assistants and support staff be regulated as a single group within a single framework including some shared standards and some discipline-specific standards?
3. Your responses to these questions should be sent no later than **2nd July 2004**.

If you are replying in writing please indicate whether you are responding as an individual or on behalf of any organisation and what Country you reside in. If you are responding as an individual it would be helpful if you could indicate whether you are a member of the public, an employer, an assistant or member of support staff (currently unregulated) or an existing regulated professional (please specify). This document is available electronically on the Department of Health website at: www.dh.gov.uk/consultations

You can respond via the website or **in writing** to:

Regulation of Health Care Staff in England and Wales Consultation  
Health Regulatory Branch  
Department of Health  
Room 2N35B  
Quarry House  
Quarry Hill  
Leeds LS2 7UE

The information you send us may need to be passed to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation. We will assume that you are content for us to do so unless you specifically include a request to the contrary in the main body of your reply. If you are replying by email, your consent overrides any confidentiality disclaimer that is generated by your organisations IT system.
Annex B
Partial Regulatory Impact Assessment

Title

Regulation of Health Care Staff in England and Wales

Issue

1. There has long been concern that a large proportion of healthcare including some previously provided exclusively by registered professionals in both the NHS and the private sector is now delivered by staff, both professionally and lesser-qualified, who are not statutorily required to meet specific standards of training, competence, practice or conduct. These groups are:
   - healthcare support staff including healthcare assistants, scientific support staff and therapy assistants;
   - professions such as Operating Department Practitioners, applied psychologists, other talking therapists including psychotherapists, and unregulated healthcare scientists.

2. This leaves the public who receive healthcare from these groups vulnerable to damage, including potential fatality, from healthcare staff whose fitness to practise may be impaired by poor health, bad character or conduct, or lack of competence. There have been many concerns and a few high profile cases in recent years. Examples of these are:
   - the death during heart surgery of a baby attended by an incompetent clinical perfusionist;
   - cervical smears incorrectly tested leading to wrong cancer diagnoses and delays in treatment or unnecessary anxiety;
   - numerous complaints about sexual and psychological abuse and exploitation of patients by psychologists and psychotherapists, instances where healthcare assistants have given inadequate or incorrect treatment or failed to record treatment properly.

3. The lack of regulation also means it is impossible to prevent practitioners who are struck off registers of regulated professions from resuming healthcare work in an unregulated capacity. There is anecdotal evidence of nurses struck off their professional register gaining work as healthcare assistants – this is a common resort of nurses suspended or struck off by their regulator as an alternative means of earning a living. Where the reason for their striking off relates to practice or conduct which could equally apply to practice in a supporting role (the majority of cases) patients are still subject to the same risks as the regulator sought to avoid by striking them off a professional register. The Government has recently enacted legislation to regulate support and professional staff in social care, and is reforming existing regulation for healthcare staff to strengthen public protection. This is part of that programme.

4. The Government announced its intention to publish proposals for the effective regulation of support workers in the NHS Plan in July 2000. This has been broadly welcomed by the public and by professions and staff groups.
Objective

5. The Government's objective is to:
   • ensure public protection by excluding unfit practitioners from the healthcare workforce;
   • set national occupational standards to improve competence of healthcare staff and quality of patient care;
   • provide a mechanism for dealing with practitioners who become unfit to practise because of ill health, misconduct or lack of competence; and
   • ensure that training and competence standards promote a flexible, multi-skilled workforce better able to provide patient-centred services, by providing links with and access to other existing professional healthcare training.

Risk assessment

6. If the current situation remains there is no satisfactory way of ensuring that unfit, even dangerous staff do not resume healthcare with different employers. Poor practice or conduct by these staff will be more likely to go undetected or untreated with consequent damage, including potential fatality, to patients.

7. In addition the public and employers are likely to have their confidence in the regulatory bodies, and in the health service itself, further damaged. If professional staff whose fitness to practise is impaired cannot be effectively dealt with by the regulatory bodies this seriously impedes the provision of good quality patient care.

8. The number of staff whose practice would improve from being required to meet specific standards would be at least 250,000 (approximately 50,000 professional staff, 200,000 support staff). Of these, based on the experience of the Nursing and Midwifery Council, about 0.25% of registrants per year (625) staff might need investigation and/or action taken to prevent or restrict their unsafe practice. Although this is a very small proportion of the total, each case could have serious consequences for patients and increasing loss of confidence in healthcare for the general public. The number of staff prevented from existing regulated practice who might work in an unregulated capacity could be 200 per year, but all these would pose significant risk to patients.

Options

9. Three options have been identified:
   1. Do nothing.
   2. Introduce voluntary, optional standards (either set and registered by staff organisations, where employers would choose to employ only those staff on that register; or set by the employers themselves. Neither would be statutorily compulsory for practice, just required by the individual employer) and rely on employers’ local disciplinary procedures to tackle poor performance.
   3. Introduce mandatory standards for all practitioners required by statute, backed up by fitness to practise mechanisms operated by a national regulatory body.
**Option 1** no change.

**Option 2** could set national benchmark standards to improve practice and give some measure of protection but could still allow unsatisfactory staff to resume work with different employers. Unless all employers carry out rigorous pre-employment checks there could still be risk to patients from unsuitable or dangerous staff. Nevertheless this may provide an adequate level of protection in proportion to the estimated risk, for some support staff.

**Option 3** would give the best safeguard to patients and the public. It would set and maintain standards for all practitioners and would provide a national mechanism for sharing registration information with other statutory regulatory bodies, to prevent those struck off one register from seeking other work in healthcare.

**Issues of equity or fairness**

10. The proposed measures would impact equally on the whole healthcare sector. They would affect self-employed professionals equally whether they provided services to the NHS or to private patients, as all would have the same obligations to be on the professional register and pay the same registration fees. Their impact on the employers of health professionals would again be similar whether the employer is in the public or private sector. There would be some greater impact than now, since all staff currently unregulated (or moving from voluntary to statutory regulation) would have to demonstrate they could meet new standards of fitness to practise, and would be required to pay a registration fee. Employers would need to carry out pre-employment checks on new staff and to provide facilities for training. However those in the public sector and some in the private sector do this already, and this impact could be reduced to the extent that training based on national standards would obviate the need for employers to design their own. Existence of a statutory national register would also make pre-employment checks easier. Staff would similarly benefit from acquiring nationally recognised qualifications which could link into other health and social care training, opening up greater career opportunities.

**Benefits**

11. **Option 1** Would disadvantage patients and the public. It would save staff paying a registration fee but would not give them the benefit of nationally recognised or transferable qualifications.

12. **Option 2** There will be some benefit in terms of strengthened public protection but significant loopholes will remain because those who wish to evade regulation may do so and still practise despite poor performance, since registration will not be compulsory. Providing safer services is unlikely to lead to much greater demand, since such services are already used when needed and resourced – these measures will affect quality rather than quantity. This option would impose some extra burden on all employers in terms of redesigning employment contracts but this could be offset by gains in service quality and more flexible, efficient workforce. For staff there would be some benefit from meeting national occupational standards and achieving nationally recognised, transferable qualifications which would open up new career opportunities to them and increase workforce flexibility.

13. **Option 3** This would give the best benefit in terms of most comprehensive public protection and greatest confidence that unfit practitioners would be prevented from working in healthcare. It would benefit staff by setting recognised professional or occupational standards as a framework for developing their practice and further career development; by providing a fair and fast process for determining a registrant’s fitness to practise where this is called into question; and by improving public perception.
of healthcare staff. It would benefit employers by providing information on staff being recruited, and support from a regulator in dealing with unfit practitioners.

**Sector affected**

14. The following groups providing healthcare in the public and private sectors:

- Healthcare support staff including healthcare assistants, scientific support staff and therapy assistants;
- Professions such as Operating Department Practitioners, applied psychologists, other talking therapists such as psychotherapists, and unregulated healthcare scientists;
- Employers of these staff: NHS Trusts, Primary Care Trusts, private healthcare employers, and self-employed practitioners.

**Compliance Costs**

15. **Option 1** There are no additional costs associated with this option.

16. **Option 2** There could be small costs on charities, voluntary organisations and businesses who employ such staff, arising from providing standardised training and staff quality assurance (pre-employment checks). However many such businesses already carry out these activities so additional cost could be small or non-existent. Staff themselves who chose to be regulated would incur a small cost (in the region of at least £20 per registrant per year, with scope for minimising registration fees if regulation costs are shared with other existing groups of registrants). It is not possible to know, in advance of consultation, how many practitioners would adopt voluntary regulation.

17. **Option 3** There will be small costs on charities, voluntary organisations and businesses who employ such staff, arising from providing standardised training and staff quality assurance (pre-employment checks). However many such businesses already carry out these activities so additional cost could be small or non-existent. Staff themselves would incur a small cost (in the region of at least £20 per registrant per year, with scope for minimising registration fees if regulation costs are shared with other existing groups of registrants). For those healthcare professionals already voluntarily regulated the charge would be minimal and could even reduce.

18. The number of staff who would be required to meet specific standards of practice would be at least 250,000 (approximately 50,000 professional staff, 200,000 support staff). We estimate the total cost borne by individual healthcare practitioners to be between £5 million to £20 million. This would cover renewal of registration at least once every three years; employment of staff by one of the existing regulatory bodies to handle such as registration and fitness to practise procedures (investigations and hearings of allegations of unfitness to practise by panels of regulator members who could apply sanctions such as suspension, requirement to undergo training or supervised practice or striking off from the register). This whole operation is estimated at a cost of between £5–20 million per year, depending on numbers of registrants, extent of standards setting/quality assurance of education and numbers of unfitness to practise allegations to be investigated. The Government’s preference is for regulation to be undertaken by one or more of the existing regulatory bodies which would need some injection of funds (up to £6 million over two years when this funding can be made available) for start-up costs but the ongoing administration costs would thereafter be met from registrants’ fees. Results of the consultation may reduce this cost if it can be minimised by making use of existing regulatory bodies. These would still need some start-up financial assistance but it could be more in the order of £2 million.
Impact on Small Businesses

19. The likely burden on small businesses would not be more onerous, in relation to size, than it would be for larger concerns although we accept that small operators would normally have less administrative capacity.

Competition Assessment

20. We have studied the market for this area and found it had many different health carers. Whilst the changes recommend will increase barriers to entry slightly, these are not significant enough to deter new entry. No other concerns were identified and we did not feel the need to undertake a detailed assessment.

Securing Compliance

21. Consultation is planned to take place from February to July to find out whether professional bodies, staff and employers would chiefly support, and therefore comply with, Options 2 or 3.

Summary and Recommendations

22. We are exploring Options 2 and 3 further by means of comprehensive consultation planned to finish in July 2004, of which this partial RIA forms part. Final recommendations will follow after consultation.

Future Implementation Review

23. If consultations do not yield information on the likely burden of complying with these arrangements, we will review this RIA in light of experience within 3 years of implementation of any resulting regulations.

Contact

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Annex C
People Consulted

Academy of Medical Royal Colleges
Action for Blind People
Action for Sick Children
Action for the Victims of Medical Accidents
ADSS
Age Concern
All Wales Committee for Healthcare Professions
All Wales Medical Directors Group
Allied Health Professions Forum
Amicus
Amalgamated School Nurses Association
Arthritis Care
Association of British Insurers
Association of British Paediatric Nurses
Association of Child Psychotherapists
Association of County Councils
Association of Directors of Social Services
Association of Human Health Resources Managers
Association for the Improvement of Maternity Services
Association of London Government
The Association of Operating Department Practitioners
Association of Optometrists
Association of Practitioners in Learning Disabilities
Association of Professional Music Therapists
Association of Professional Ambulance Personnel
Association for the Protection of Rights of Private Patients
Association of Radical Midwives
Association for Residential Care
Association of Supervisors of Midwives
Association of University Teachers
Association of Welsh Community Health Councils
BMI Healthcare
British Association of Arts Therapists
British Association of Cancer United Patients (BACUP)
British Association of Drama Therapists
British Association of Medical Managers
British Association of Prosthetists and Orthotists
British Association of Social Workers
British Confederation of Psychotherapists
British Council of Disabled People (BCODP)
British Deaf Association
British Dental Association
British Diabetic Association
British Healthcare Association
British Heart Foundation
British Medical Association
British Nursing Corporation Ltd
British Orthoptic Society
BUPA Health Services Ltd
Cabinet Office
Carers National Association
Carers National Association in Wales
Centre for the Advancement of Inter-professional Education
Chartered Society of Physiotherapy
Children's Society
Clinical Perfusion Scientists of Great Britain
College of Health
College of Occupational Therapists
College of Optometrists
College of Pharmacy Practice
Commission for Health Improvement
Commission for Racial Equality
Office of the Commissioner for Public Appointments
Committee of Scottish Higher Education Principals
Committee of Vice-Chancellors & Principals of the Universities of the United Kingdom
Community and District Nursing Association
Community Hospitals Association
Community Hospitals Group plc
Community Mental Health Team Management Association
Community Practitioners & Health Visitors Association
Community Psychiatric Nurses Association
Company Chemists Association
Compass Group plc
Constructive Dialogue for Clinical Accountability
Consumers Association
Continuing Care Conference
Council of Deans and Heads of University Faculties of Nursing, Midwifery and Health Visiting
Council of Heads of Medical Schools and Deans of United Kingdom Faculties of Medicine
Council of Local Education Authorities
Disability Rights Commission
Disability Wales
De Montfort University
Department for Education and Skills (DfES)
Education & Training Consortia in England: Chair
                       Chief Officer
Education and Training Group in Wales
Employers Organisation
Equal Opportunities Commission
Federation of Healthcare Science
Federation of Ophthalmic and Dispensing Opticians
Foundation for Integrated Medicine
Further Education Funding Council
General Chiropractic Council
General Dental Council
General Healthcare Group plc
General Medical Council
General Optical Council
General Osteopathic Council
General Social Care Council
GMB Union
Greater London Assembly
Regulation of Health Care Staff in England and Wales

Guild of Healthcare Pharmacists
Healthcare Tutors Association
Health Professions Council
Health and Safety Executive
Health Professions Wales
Health Service Commissioner
Healthcare Schools and Faculties of Universities in the UK: Dean and Head
Healthwork UK
Heathcroft Services
Help the Aged
Higher Education Funding Council for England
Higher Education Funding Council for Wales
Independent British Hospitals plc
Independent Care Management Ltd
Independent Healthcare Association
Independent Midwives Association
Institute of Biomedical Science
Institute of Health Services Management
Institute for Learning and Teaching
Joint Committee for Post Graduate Training in General Practice
Joint Committee of Professional Nursing, Midwifery and Healthvisiting Organisations
JM Consulting
King’s Fund College
Leonard Cheshire Foundation
Liaison Committee of Royal Colleges and Faculties in Wales
Local Authority Social Services Departments in England and Wales: Director
Local Authority Social Work Departments in Scotland: Director
Local Government Association
Local Government Management Board
Local Health Groups in Wales
Long-Term Medical Conditions Alliance
Department of Health and Social Security, Isle of Man
Maternity Alliance
MENCAP
Mildmay UK
MIND
MSF

National Association of Citizens Advice Bureaux
National Association of Theatre Nurses
National Audit Office
National Care Homes Association
National Childbirth Trust
National Children’s Bureau
National Children’s Homes
National Confederation of Registered Residential Care Association Homes
National Consumer Council
National Council for Hospices and Specialist Palliative Care
National Council for Voluntary Childcare Organisations
National Council for Voluntary Organisations
National Institute for Clinical Excellence
National Institute for Social Work
National Pharmaceutical Association
Neonatal Nurses Association
Nestor Healthcare
NHS Confederation
NHS Consultants Association
NHS Education Scotland (NES)
NHS Quality Improvement Scotland (NQIS)
NHS Trusts in the UK Chair
   Chief Executive
   Nurse Executive Director

NHS University (NHSU)
NHS Wales Equality Unit
Nuffield Hospitals
Nuffield Trust
Nurse Education Forum Wales
Nurse Executive Wales Group
Nursing and Midwifery Council
Nurse Welfare Service
Patients Association
Patients Concern
Patients Forum
Patients Network
PPP Healthcare Group
Practice Nurse Association
Prevention of Professional Abuse Network
Privy Council Office
Qualifications and Curriculum Authority
Quality Assurance Agency
Queen’s Nursing Institute
Recruitment and Employment Confederation
Registered Nursing Home Association
Royal Association for Disability & Rehabilitation
Royal British Nurses Association
Royal College of Midwives
Royal College of Nursing
Royal College of Occupational Therapists
Royal College of Speech and Language
Royal National Institute for the Blind
Royal National Institute for the Deaf
Royal Pharmaceutical Society of Great Britain
St John Ambulance
St Martins Hospitals Ltd
School of Health Related Research
SCOPE
Society of Clinical Perfusionists
Social Care Institute for Excellence
Society of Local Authority Chief Executives
The Society of Clinical Perfusion Scientists of Great Britain and Ireland
The Society of Radiographers
Special Health Authorities in England: Chair
Chief Executive
Specialised Health Services Commission for Wales
Specialist Training Authority
Standing Conference of Principals
Standing Conference of Voluntary Organisations for People with a Learning Disability in Wales
Standing Medical Advisory Committee
Standing Nursing and Midwifery Advisory Committee
Theatre Personnel Nation-wide
Department of Trade and Industry
Trade Union Congress
Training Organisation for the Personal Social Services
HM Treasury
Trust Nurses Association

Unison
Universities UK

Wales Association of Community and Town Councils
Wales Council for the Blind
Wales Council for the Deaf
Wales Council for Voluntary Action
Wales Office of Research and Development
Welsh Combined Centres for Public Health
Welsh Consumer Council
Welsh Dental Committee
Welsh Development Agency
Welsh Institute for Health and Social Care
Welsh Language Board
Welsh Local Government Association
Welsh Medical Committee
Welsh Nursing and Midwifery Advisory Committee
Welsh Nursing and Midwifery Group
Welsh Office
Welsh Partnership Forum
Westminster Healthcare plc