# PARTIAL REGULATORY IMPACT ASSESSMENT

## NATIONAL HEALTH SERVICE REFORM AND HEALTH CARE PROFESSIONS BILL

## DEPARTMENT OF HEALTH
## 9 NOVEMBER 2001

## SUMMARY

1. This partial regulatory impact assessment provides a summary of the Government's assessment of the impact of the National Health Service Reform and Health Care Professions Bill on businesses and voluntary organisations, at the point of the Bill's introduction. This document should be read in conjunction with the explanatory notes and the Bill itself as introduced.

2. The key measures in the Bill are:

    1. Health Authorities to be replaced with a smaller number of Strategic Health Authorities, and the planning and commissioning functions of Health Authorities to be devolved to Primary Care Trusts.
    2. Creation of Local Health Boards in Wales, to extend the current role of Local Health Groups.
    3. Most of the funding allocated to HAs, to be allocated by the Secretary of State directly to Primary Care Trusts.
    4. New arrangements to strengthen the Commission for Health Improvement (CHI) and its independence.
    5. Abolition of Community Health Councils (CHCs) in England and of the Association of Community Health Councils of England and Wales, and their replacement by a stronger system of patient and public involvement.
    6. A duty of partnership on NHS bodies and the Prison Service, to work together in carrying out their functions as they relate to health services for prisoners.
    7. A duty on each Local Health Board and each Local Authority in Wales to formulate and implement a 'health and well-being strategy'.
    8. The creation of a Council for the Regulation of Health Care Professionals to oversee the activities of the various regulatory bodies of the health care professions.
    9. Appeal cases in relation to 'fitness to practise' issues to be transferred from the Judicial Committee of the Privy Council to the High Court in respect of those professions where this is not already the case.
    10. Extension of the powers conferred by section 60 of the Health Act 1999 (which deal with the modification of legislation governing the regulation of health care professions) to bring those powers in

respect of the profession of pharmacy more into line with those for other professions.

3. The majority of these measures affect in the main the internal operations of NHS organisations, or the arrangements between the NHS and other statutory bodies. Our assessment is that the Bill as a whole does not have a significant impact on businesses or voluntary organisations. Some of the measures, namely measures 7 and 8 will have a very small impact as set out in Annexes A and B.

**Clauses 1 to 5 – NHS bodies and their functions: England**
**Clause 6 – Local Health Boards (in Wales)**
**Clauses 7 to 10 – Financial arrangements: England and Wales**

4. The regulatory measures will directly affect NHS bodies only, and are unlikely to impose any obligations on small businesses, charities or voluntary organisations. Voluntary organisations and community groups may need to address their attentions to different NHS bodies to the ones they liaised with before.

5. The proposed legislation will pave the way for administrative and organisational changes that should deliver positive benefits, directly and indirectly, for staff, health care professionals, patients, service users, voluntary organisations, charities and many others, in terms of service improvements. It is expected that most voluntary organisations, small businesses and charities will warmly welcome the shift in the balance of power to a more local and accessible level.

**Clauses 11 to 14 - Quality**

6. In the main, these clauses concern changes to the internal, and reporting arrangements of the Commission for Health Improvement, and its relationship with the Department of Health and the NHS. In two areas, however, the changes do relate to businesses and the non-Government sector.

7. Clause 13 will allow CHI to gain, in pursuit of its functions, entry to non-NHS premises such as GPs' surgeries and community pharmacies, etc. However, CHI will be required to give reasonable notification of its intention to gain entry, and, given its statutory status and its remit to pursue quality in the interests of patients or customers, it is anticipated that this power will only be used on an exceptional basis.

8. Clause 14 will establish within CHI an 'Office for Information on Health Care Performance' which will be concerned with the collection and analysis of information, and with the validation of information collection systems. In carrying out this role, CHI will request information from a range of bodies including some, such as the Royal Colleges, that are not part of central Government or the NHS. However, the Bill will not

require such bodies to produce the information, which will be obtained on a voluntary basis or under contractual arrangements.

**Clauses 15 – 20 – Patient and public involvement**

9. These clauses provide strengthened arrangements by which patients, their carers, their representatives and the public can have a greater say over the services they receive.

10. A Patients' Forum (PF) for every NHS Trust and PCT will be established to represent the interests of patients and the public locally. A Commission for Patient and Public Involvement will be set up to support PFs and to act as a voice for patients and the public at national level.

11. Membership of PFs from voluntary and charity groups will not be imposed. There will be no financial burden on voluntary organisations through forum membership; it will be an issue of time commitment for members. Expenses such as travel costs etc will be reimbursed. Relevant organisations will be invited to apply for membership. The likely burden will be attendance at Forum meetings, with additional work involved in inspecting services. Forum members will also need to canvass the views of the local patient population.

**Clause 21 – Joint working with the prison service**

12. These provisions will clarify the need for partnership working between the NHS and prisons; and make provisions for discretionary delegation of functions and pooling of budgets between the Prison Service and the NHS, contributing to the delivery of better services. There will be no regulatory impact on business, charities or voluntary organisations.

**Clause 22 – Health and well-being strategies in Wales**

13. See Annex A.

**Clauses 23 to 27 – The Council for the Regulation of Health Care Professionals**

14. See Annex B.

**Clauses 28 to 32 – Appeals**
**Clause 33 – Regulation of the profession of pharmacy**
**Clauses 34 to 40 – Miscellaneous**

15. Our assessment is that there is no significant impact on businesses or voluntary organisations as a result of these provisions.

**ANNEX A**

## PARTIAL REGULATORY IMPACT ASSESSMENT

## CLAUSE 22 - HEALTH AND WELL-BEING STRATEGIES IN WALES

## ISSUE AND OBJECTIVE

### Issue

1. These provisions give effect to the National Assembly for Wales' commitment to ensure partnership working in the development and implementation of local strategies for health and well being as expressed in *Improving Health in Wales* (the NHS Plan in Wales). The provisions will place a duty on each newly created Local Health Board (LHB) and each local authority in Wales to formulate and implement a health and well-being strategy for the area.

2. The National Assembly intends to take direction making powers to ensure that NHS Trusts co-operate with the LHB and LA partners in developing the Health and well-being strategy. In formulating and implementing the health and well-being strategy, the LHB and LA partners will be under a duty to co-operate with other persons and organisations namely representatives from the voluntary sector, NHS trusts, private sector service providers and Community Health Councils. Representatives of the voluntary sector, independent sector and CHC 'partners' will not be under a reciprocal duty of co-operation. We expect them to want to work in partnership because of the benefits to be derived from so doing. Should LAs or LHBs fail to undertake strategy preparation as required by these provisions the National Assembly could seek to direct them to do so. The Assembly could, in the event, seek a judicial review of a LA or LHB decision not to act within the terms of the proposed provision.

3. Each local strategy for health and well-being will have a direct relationship with the local Community Strategy required under section 4 of the Local Government Act 2000. It will also link to local Children and Young People's Partnerships that are being established to provide focus in strategy and planning for services for children and young people. The strategy for health and well being will in turn provide a framework within which more detailed service delivery and operational plans can be taken forward by partners. The Strategy should therefore come to replace the strategic elements of the Health Improvement Plans and Social Care Plans in Wales and contribute to the health-related elements of the Community Strategy.

4. The provisions allow the Assembly to:

- set the time period to which the strategy will apply;
- specify the components of the strategy in regulations;
- require reports on strategy formulation and implementation.

**Objective**

5. To provide the National Assembly for Wales with the necessary powers to require the preparation and implementation of a health and well-being strategy for each local government area. If this approach is not adopted, planning and service delivery for health and well being will be undertaken on a more piece-meal basis. We are seeking to achieve quality and consistency.

**RISK ASSESSMENT**

6. Although regulatory in purpose and effect in the context of these regulations there is no perceived hazard or situation, which would lead to any harm or detriment to any individual or organisation.

7. A statutory model is being sought to ensure a consistent approach to partnership working across Wales and to provide the National Assembly with powers to ensure a partnership working in circumstances where for some reason LAs and LHBs are less than willing to work in this way.

8. The provisions are about a way of working and give effect to commitments made in *Improving Health in Wales* to more fully engage a wider stakeholder group in planning for health and well being Wales. The biggest single risk to small businesses (the group most likely to have an interest in these provisions are the owners and managers of nursing and residential homes), the voluntary sector and charities would be if the proposed legislation were not passed – thus effectively allowing each LA and LHB to take an individual and less structured approach to engagement with the wider stakeholder group. If these organisations are not fully engaged we will be less well equipped to develop the whole system approach to planning and service delivery for health and well being to which the Assembly is committed. In which case the commitments about inclusiveness made in *Improving Health in Wales* would not be effectively delivered and the full benefits would not be achieved.

**OPTIONS**

**Option 1**

9. To do nothing and maintain the status quo. This leaves the system open to the risks described in paragraphs 6 to 8.

**Option 2**

10. Implement the proposed measure.

**ISSUES OF EQUITY AND FAIRNESS**

11. None. The NHS will remain a comprehensive service based on clinical need and not on the ability to pay.

**BENEFITS**

**Option 1**

12. The wider group of stakeholders will be involved in setting to agenda to a greater or less extent across Wales. Some may argue that this local autonomy is beneficial, but in terms of developing consistent, comprehensive and equitable health and well being systems across Wales, on balance that degree of local discretion is a dis-benefit. Evidence of joint and partnership working under current arrangements is that the independent and voluntary sectors are brought into the system inconsistently and that this does not make for coherent resource management, service delivery or performance management.

**Option 2**

13. A wider group of stakeholders will be directly involved setting the agenda for the improvement of health and well being in the local area. The National Assembly is developing a partnership model in which policy makers, service commissioners and providers, patients, users, carers and the wider community have a role and a say in how services are designed, developed and delivered.

14. Services providing businesses, voluntary organisations and charities will benefit from being more directly involved in the planning stages of service delivery and development. They will have the opportunity to bring more influence to bear on the health and well being system than they do under existing planning and commissioning arrangements.

15. Voluntary organisations and charities which have a campaigning and/or advocacy role in the health and well being system will have the opportunity through their partnership role in the development of a health and well-being strategy for the area to bring more influence to bear on decisions about service delivery, priority setting and such like than they do under existing planning and consultation arrangements.

16. Improved service delivery to promote health and well being will benefit the wider community as well as patients, users and carers.

17. The development of health and well-being strategies is central to the National Assembly's commitment to promote joint working between the various agencies that have a statutory and/or non-statutory role in the health and well being agenda in the local area. Decision-making will be more locally based, more inclusive and more transparent. There will be benefits for individuals and, indirectly, for the organisations with which they are involved as a result of the better integration and the NHS, social care, housing, public health, health promotion services.

**Quantifying and valuing the benefits**

18. It is difficult precisely to quantify the benefit to be derived by businesses, voluntary organisations, charities, patients, users and carers and by the wider community and organisations, but a more integrated, transparent and inclusive approach to health and well being planning and service delivery will have direct and indirect benefits for the health and well being of the entire population.

**COSTS**

19. The types of businesses most likely to be affected by these proposals are nursing and residential homes and the umbrella organisations which seek to represent the common interests of homeowners and managers. The National Assembly is firmly committed to ensuring that these private sector nursing and social care providers are fully involved in the strategy setting and planning processes at the local level. This reflects the recognition of the significant capacity which they bring to the health and social care system.

20. The types of voluntary organisations and charities most likely to be affected by these proposals are those that have a campaigning and/or advocacy role in respect of patients, users and carers. Community Health Councils (CHCs) will be among the bodies with which local authorities and local health boards are required to work in partnership to prepare health and well being strategies.

21. It is difficult at this stage to precisely quantify the costs to these business, voluntary sector and charitable bodies of engagement in the development and implementation of local health and well-being strategies, as the final terms of engagement have not yet been determined. Some of the terms will be set out in National Assembly guidance after consultation, and partners at the local level will determine some of the terms of engagement. Costs are likely to arise from meetings and administration and the staff time, preparatory work and travel and subsistence costs associated with these activities which will be identifiable once the frequency of meetings and methods of working have been agreed. To some degree these costs can be off-set against the costs to these organisations of engagement in current more traditional consultation arrangements undertaken e.g. by Health

Authorities on Health Improvement Programmes and Local Authorities on Social Care Plans.

22. The NHS Plan in Wales implementation strategy established several task and finish groups to advise the Minister on implementation of the Plan. The joint working task and finish group which includes representatives of the private sector service providers and voluntary and charitable organisations recommended the partnership model of health and well-being strategy development and implementation to which this RIA refers. The private sector service providers', voluntary and charitable organisations', and CHC representatives on the task and finish group judged that their local networks would be able to work with the National Assembly and local statutory partners to establish the most effective, efficient, equitable and economic means of engagement. The balance of opinion is that the benefits of engagement and involvement far out-way the costs.

**Other costs**

23. Costs to the National Assembly will involve the provision of guidance, advice and the costs of monitoring the system and resolving possible disputes. These costs can largely be offset as the National Assembly is currently engaged with such activity. Under the new arrangements our role could and should be more coherent and joined-up as we will be working with a more joined-up external system.

24. The costs to LA and LHBs will largely be administrative and consultative and can be offset against current costs of consultation and collaborative working. Any additional costs associated with health and well-being strategies should be offset by benefits of more integrated approach to service provision and delivery.

25. There will be no absolute or statutory requirement on businesses, or voluntary/independent sector providers, to participate in the preparation of a health and well being strategy. The Assembly will issue guidance to LHBs and Local Authorities, as the statutory partners, on how to involve stakeholders. This will require them to invite organisations to work with them on strategic preparation and development. It will be up to them to decide whether or not to take an active part.

**Compliance costs for a typical business**

26. As described in paragraphs 19 to 22.

**Impact on Small Business**

27. The potential cost to small businesses and their umbrella bodies is covered in paragraphs 19 to 22.

## CONSULTATION

28. The proposals have been developed as part of the highly inclusive and consultative approach to implementation in *Improving Health in Wales*. The model has been developed by a task and finish group with membership from all stakeholder groups.

29. The model is currently part of a wider three-month public consultation exercise on the structure of the NHS in Wales (principally proposals for the establishment of Local Health Boards in Wales). The consultation closed on 19th October. Responses are currently being considered.

30. The detail of the partnership arrangements for the development of health and well being strategies will be subject to National Assembly regulations and guidance, which will be consulted upon fully prior to implementation of the proposals.

## SUMMARY AND RECOMMENDATION

31. The National Assembly has committed itself to a partnership model for the development of local health and well-being strategies. The model seeks to fully embrace the interests and expertise of statutory and non-statutory partners including private sector service providers, voluntary bodies and charitable organisations. These bodies have been fully involved in the development of the model to which the provisions and this assessment refers. The balance of opinion of the representatives on the task and finish group is that the benefits of engagement in a more integrated, transparent and inclusive approach to planning and service provision for health and well being far out-weigh the costs.

32. The proposed legislation provides the statutory framework to ensure this inclusive and integrated way of working.

## ENFORCEMENT, SANCTIONS, MONITORING AND REVIEW

33. It is known from the inclusive way in which the model has been developed that most voluntary organisations, small businesses and charities welcome the proposals because of the benefits to be derived by a way of improved planning and service delivery for health and well being.

34. It is not anticipated that the proposals will require any additional effort or expenditure for the general public so that enforcement is not an issue. It is not envisaged that sanctions would ever be necessary.

35. The proposals envisage that the National Assembly will receive an annual report from the ‘partnership’ on its health and well-being strategy development and implementation. This report will contribute to the performance management regimes for the NHS and local government in Wales.

36. *Improving Health in Wales* and all associated changes and developments will be under the scrutiny of the Health and Social Service Committee of the National Assembly for Wales.

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**ANNEX B**

## PARTIAL REGULATORY IMPACT ASSESSMENT

## CLAUSES 23 TO 27 - THE COUNCIL FOR THE REGULATION OF HEALTH CARE PROFESSIONALS

## ISSUE AND OBJECTIVE

### Issue

1. The 8 regulatory bodies for health professions* have recognised that they need to modernise and better co-ordinate the way in which they carry out their work. They recognise the need to become more accountable to patients and the public, and to the providers of health care. Some differences in the approach to regulation taken by the different professional bodies need to be made more consistent. The document, *Modernising Regulation in the Health Care Professions*, published in August, set out the Government's proposals in this area, which have the same broad aims.

### Objective

2. The provisions on professional regulation will enable three key objectives to be met:

   - decisions on the fitness to practise of professionals on the different bodies' registers, modernising and streamlining the way appeals from decisions on fitness to practise are handled;
   - establishing the Council for the Regulation of Health Care Professionals (CRHP) promised in the NHS Plan, and recommended in the Kennedy Report, in order to help co-ordinate common approaches across the professions;
   - strengthening and clarifying the accountability of the 8 regulators by placing them in a common accountability framework supervised by the new CRHP; this new accountability will not cut across historical lines of accountability which already exist.

## RISK ASSESSMENT

3. These measures are proposed in order to make a step change in the effectiveness of operation of regulators, to avoid the risks to patients and the public which could be posed by regulators working sub-optimally. The particular harm which would follow if these measures

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* the General Medical Council, the UK Central Council for Nursing, Midwifery and Health Visiting, the Royal Pharmaceutical Society of Great Britain, the General Dental Council, the Council for the Professions Supplementary to Medicine (which covers e.g. physiotherapists), the General Optical Council, the General Osteopaths Council and the General Chiropractic Council.

were not taken would be the risk of a slide in public and professional confidence that the regulators were capable of protecting patients or being fair to registrants.

4. There are two other areas of risk. Firstly, without change the current costly and time-consuming process for resolving appeals would continue. We estimate that this consumes 10% of the sitting time of the Judicial Committee of the Privy Council at a cost of approximately £80,000 per year (and rising).

5. Secondly the regulatory bodies would continue to function in a less coordinated way, resulting in waste, delay and risk to patient safety (for example when a person with dual registration who is barred from practising one profession continues to practise the other).

**OPTIONS**

6. Two options have been identified:

   1. Do nothing;
   2. Legislate as outlined in the *NHS Plan* and the Kennedy Report.

7. Option 1 would not achieve the evident changes required.

8. Option 2 involves legislating to set up a Council for the Regulation of Health Care Professionals which will be the guarantor of the public interest, and co-ordinate and align the efforts of the existing regulatory bodies. The legislation proposed would give this Council reserve powers to direct existing regulators to adopt new rules to achieve a particular object, so as to ensure that it had sufficient influence to achieve its goals. On fitness to practise appeals, legislation would re-route those which currently go to the Judicial Committee of the Privy Council so that in future all such appeals would be heard by the High Court (in Scotland, the Court of Session).

**Issues of equity or fairness**

9. The proposed measures would impact more or less equally on the whole healthcare sector. They would affect self-employed professionals equally whether they provided services to the NHS (e.g. General Practitioners) or to private patients, as all have the same obligations to be on the professional register and pay the same fees etc. Their impact on the employers of health professionals would again be similar whether the employer is in the public or private sector. The likely burden on small businesses would not be more onerous, in relation to size, than it would be for larger concerns although small operators would normally have less administrative capacity.

## BENEFITS

10. Option 1 - there are no benefits to patients or the professional bodies.

11. Option 2 - this option is the best trade-off between reducing the risks described in paragraph 2 and maintaining the professional “ownership” of regulation systems which is a strong feature of the current system and helps deliver high levels of voluntary compliance.

## COMPLIANCE COSTS

12. These changes would have a negligible effect on charities, voluntary organisations and businesses, including self-employed professionals. Professionals would continue to be regulated by their existing bodies but this regulation would become more transparent and accountable to the public and to the providers of health services. This should indeed confer benefits on those affected by:

    - streamlining (in the case of appeals) the process for determining a registrant’s fitness to practise where this is called into question;
    - removing regulatory obstacles to a more fluid movement between different healthcare professions, leading to more rewarding and varied careers with greater opportunities for those qualifying by unconventional routes e.g. in-service training;
    - improving the public perception of the professions affected.

13. It is intended that the new Council for the Regulation of Health Care Professionals will oversee the performance and efficiency of the 8 Regulatory Bodies. As such, officials anticipate that its impact on individual professionals will be minimal.

## SECURING COMPLIANCE

14. The preferred option best combines the existing incentives for voluntary compliance (e.g. with regulators’ guidance such as *Good Medical Practice*) with encouragement to the regulators to voluntarily improve their performance.

## SUMMARY AND RECOMMENDATION

15. The assessment has indicated that option 2 would deliver significant benefits with very low compliance costs. We recommend adopting option 2.

## CONSULTATION

16. Our proposals for the Council for the Regulation of Health Care Professionals were the subject of public consultation earlier in 2001 on our paper *Modernising Regulation in the Health Professions*. The 140 responses received were overwhelmingly in favour of the principle of

proceeding in this way. Some commentators asked for the council's independence from Government to be strengthened and the Bill reflects the steps taken to do this as a result.

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