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Health and Social Care Bill

Bill 9 of 2007-08

The Health and Social Care Bill was introduced into the House of Commons on 15 November 2007 and was published the following day. It is due to have its Second Reading on Monday 26 November 2007.

It is a wide ranging Bill but has a particular focus on the regulation of organisations and individuals involved in health and adult social care services. Among the other measures included in the Bill are those designed to prevent the spread of infectious diseases and the risk of contamination; and arrangements to make one off payments to all expectant mothers in the final stages of pregnancy.

The territorial extent of the Bill varies according to the scope of the different provisions.

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Summary of main points

The Health and Social Care Bill is a wide ranging Bill but has a particular focus on the regulation of organisations and individuals involved in health and adult social care services.

Part 1 of the Bill deals primarily with the regulation of organisations. It would replace three existing Commissions to form a new *Care Quality Commission*. This new Commission would cover health and adult social services, which have until now largely been regulated separately, and would take on specific functions in relation to detained mental health patients. It would also have the power to require NHS bodies to register with it; unlike most social service providers and independent healthcare providers, NHS bodies have not so far been subject to such a requirement.

Part 2 deals primarily with the regulation of individuals. It includes provision to change the standard of proof in *fitness to practise* cases from the criminal to the civil (for those professions not already using the civil standard). This would mean that unfitness would be judged on *the balance of probabilities* rather than *beyond reasonable doubt*. Among other measures in this area, the Bill would create a new, separate adjudication body, the *Office of the Health Professions Adjudicator* (initially for doctors and opticians only); amend the powers of the existing *Council for Healthcare Regulatory Excellence*; provide for more lay representation on the councils of the relevant regulatory bodies such as the *General Medical Council*; and provide for a *responsible officer* to help identify and handle cases of poor professional performance in organisations employing or contracting with doctors.

The Government has highlighted two other priority policy areas covered by the Bill: modernising the *Public Health (Control of Disease) Act 1984*, to help prevent the spread of infectious diseases and the risk of contamination; and the provisions to make a one off payment to all expectant mothers in the final stages of pregnancy. Other measures in the Bill (contained in Part 5) include:

- A change to the general "duty of quality" in the NHS
- the transfer of the Global Sum for Pharmaceutical Services
- the power to extend membership of NHS indemnity schemes
- the extension of Direct Payments
- the abolition of the Liability of Relatives rules
- changes to "Ordinary Residence" in relation to the National Assistance Act 1948
- the creation of a power for the Secretary of State to give financial assistance to social enterprises
- the creation of the National Information Governance Board for Health and Social Care
- the abolition of the National Biological Standards Board and the transfer of its functions to the Health Protection Agency
- legislative cover for performance management and routine feedback to parents as part of the National Child Measurement Programme

Many of the measures in the Bill are indirect in that they make provision for matters to be included in Regulations or Orders in Council. The territorial extent of the various provisions is mentioned in the relevant sections of this Paper.

CONTENTS

I Introduction

The Health and Social Care Bill was introduced into the House of Commons on 15 November 2007 and was published the following day. It is due to have its Second Reading on Monday 26 November 2007.

This Library Research Paper provides a brief introduction to the Bill, its background and reactions to it. More detailed information is available in the Bill,[1] the Explanatory Notes,[2] the Impact Assessment[3] and the Department of Health's website on the Bill[4]. Many of the organisations quoted also have more detailed information about their views, both on the Bill itself and on earlier Government consultation documents leading up to the Bill.

Briefing papers on the Bill from several organizations that arrived in the Library too late to be included in the text of the Paper are attached as an appendix.

II The Care Quality Commission

Part 1 (clauses 1-90 and schedules 1-5)

The Care Quality Commission proposed in the Bill would replace three existing Commissions: the Mental Health Act Commission, the Commission for Social Care Inspection, and the Healthcare Commission (known as the Commission for Healthcare Audit and Inspection in its covering legislation). Although one of the chief objectives of the merger is to create a unified regime for health and social services, the Government has said that the way that this is being done will mostly impact on healthcare services as the most far reaching changes will be those required of the healthcare regulatory regime.[5] This Research Paper therefore gives greatest coverage to the proposals affecting healthcare.

The focus of this section of the Research Paper is on England as the functions of the proposed Care Quality Commission relate primarily to England. (Part 1 of the Bill has some impact on other parts of the UK, for example, the functions of the Mental Health Act Commission relating to Wales are being transferred to Welsh Ministers; the new Care Quality Commission would have duties and powers to inform and make recommendations to Welsh Ministers if it discovered failings relating to Welsh NHS bodies; and it would have certain powers to make arrangements with other UK Ministers).

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1 http://www.publications.parliament.uk/pa/cm200708/cmbills/009/2008009.pdf
2 http://www.publications.parliament.uk/pa/cm200708/cmbills/009/en/2008009en.pdf
3 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433
4 http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSocialCareBill/index.htm
5 Impact Assessment paragraph 3 of "provisions for future regulation of adult health and social care".

A. History

Although they are all national watchdogs, the Commissions that would be replaced by the Bill each have their own history, which their current functions reflect.

1. Mental Health Act Commission (MHAC)

The Mental Health Act Commission was created under the *Mental Health Act 1983* but its origins can be traced back to the Lunacy Commission set up in 1845, which has been described as the first national body to oversee the condition in which people have been detained for reasons of mental disorder. This body lasted until 1913 and although replaced by other arrangements for a while, in the period immediately before the MHAC was created there appears to have been no watchdog acting on behalf of detained patients.[6]

The *Mental Health Act 1983*, created the MHAC. It consists of consists of some 100 members (Commissioners), including laypersons, lawyers, doctors, nurses, social workers, psychologists and other specialists. Its current role, which relates to England Wales, is summarised on its website:

> The Mental Health Act Commission provides a safeguard for people who are detained in hospital under the powers of the Mental Health Act 1983. (This is the only part of healthcare where patients can be treated under compulsion, and necessarily there are very clear legal requirements on hospitals and the other services involved - primarily Local Authority social services). The Mental Health Act Commission is a monitoring body rather than an inspectorate or regulator. Its concern is primarily the legality of detention and the protection of individuals' human rights. In addition to a visiting programme, the Commission provides important safeguards to patients who lack capacity or refuse to consent to treatment, through the Second Opinion Appointed Doctor Service.[7]

The future of the MHAC was discussed as part of the controversial "root and branch" review of the *Mental Health Act 1983*, started in 1998 and culminating in the *Mental Health Act 2007.* In the early stages of the review it appeared to be taken for granted that there was a need for an MHAC or equivalent specialist body. However, through the various stages of the consultation process, proposals for a successor body were revised. By the time of the consultations on the first *Draft Mental Health Bill 2002* the Government was suggesting that the role of scrutinising the proper application of the proposed new *Mental Health Act* should be incorporated within a broader health inspectorate.

In July 2004, the Department of Health announced the abolition and reconfiguration of a wide range of arm's length bodies. Among the changes proposed was that the Healthcare Commission would take on the regulation of the care of people detained

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6 This account is drawn from Ian Shaw et al (chapter 2 by Jeffrey Cohen) *Understanding Treatment Without Consent*, Ashgate, 2007

7 http://www.mhac.org.uk/?q=node/30 21 November 2007

under the Mental Health Act and the Mental Health Act Commission would be abolished as part of wider changes to be made through a forthcoming Mental Health Act.[8]

In the end, proposals for a totally new Mental Health Act were dropped. The amending Act of 2007 left the MHAC in place but only pending the outcome of separate proposals to merge the Healthcare Commission and the Commission for Social Care Inspection.[9]

A more detailed account of the MHAC's powers and duties is contained in the Impact Assessment:

- MHAC members, who are publicly appointed by the Secretary of State for Health, are directed to undertake his duty to meet individual patients who are detained in NHS and independent hospitals in England under the Mental Health Act 1983. Commissioners interview patients in private and check the records relating to their detention to review whether this is in accordance with the Mental Health Act and its code of practice. The MHAC may investigate complaints made by a patient relating to their detention. It also meets with other statutory authorities involved in the detaining process (primarily Local Authorities and the police) to review and report on the overall operation of the Act in local areas. The MHAC is directed by Welsh Ministers to undertake equivalent functions in Wales.

- The MHAC is free to decide (within the usual constraints of resources) the frequency and form of these visits. It publishes an annual report of its findings for every provider organisation it has visited. That report includes any findings in relation to the interface between all relevant statutory bodies involved with the Act such as the PCT, LA and the police.

- The Secretary of State (and in Wales, Welsh Ministers) may direct the Commission to review the care and treatment of informal patients in hospitals (those not detained under the Mental Health Act) and has done so on a rare occasion for a specific purpose (the National Mental Health and Ethnicity Census).

- The MHAC does not exercise sanctions against non-compliance with the law but may advise the Secretary of State and must publish a biennial report on its activities, which is laid before Parliament.

- In addition to its visiting function, the MHAC has delegated responsibility for appointing doctors to give statutory second opinions as provided for by the Act. This is an important legal safeguard to ensure the safety and the protection of individual patients who are being treated compulsorily. The MHAC also reviews the decision of hospital managers to withhold the correspondence of detained patients in the three high secure hospitals.

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8 Department of Health, *Reconfiguring the Department of Health's Arms Length Bodies*, July 2004 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086081

9 The history of the proposals to replace the MHAC and its views on the subject are covered in *Understanding Treatment Without Consent*, Ian Shaw et al, chapter 8 by Jeffrey Cohen

2. Commission for Social Care Inspection

The Commission for Social Care Inspection (CSCI) came into operation on 1 April 2004 under the *Health and Social Care (Community Health and Standards) Act 2003.* Its current role is to register, inspect and report on adult social care services, and councils who arrange these services, in England.[10]

CSCI was designed as a single social care inspectorate, independent of the Department of Health, bringing together duties of the Department of Health's Social Services Inspectorate for evaluating the quality and performance of social services authorities (and its joint reviews with the Audit Commission) with the registration and inspection functions of the National Care Standards Commission.

The National Care Standards Commission had itself only come into being in April 2002 under the *Care Standards Act 2000,* bringing together the work of several different social care regulatory systems and also making provision for widening the range of services covered. During its brief existence, the Care Standards Commission had been the first national body to both register and inspect a wide range of social care services although it did not oversee the work of social services authorities themselves.

Immediately before that, the main piece of legislation in this area was the *Registered Homes Act 1984*, which regulated independent sector residential care homes and nursing homes (treated as two separate categories under that Act but as "care homes" under the *Care Standards Act*). Registration was with the local authority or, for nursing homes, with the health authority, not with a national body. Inspectorates were also local.

The need for reform to social services regulation had been considered for some time before the legislative changes were made. The previous Conservative Government had set up an independent review under the chairmanship of Tom Burgner,[11] which reported in 1996. Underlying arguments for reform were based on the scale of growth in social services and in particular the growth of the independent sector. More specifically, the report criticised the arrangements existing at the time for their limited coverage, inconsistency in application, lack of even-handedness between public and private sector providers, and weakness in enforcement.

Many of the themes of the Burgner Report were repeated in the reforms that followed under the Labour Government. For example, one of the Burgner Report's criticisms of the *Registered Homes Act 1984* was that it primarily concerned machinery and structures; the content of care was hardly mentioned or only in very broad terms such as that it must be "adequate", "sufficient" and "suitable". The *Care Standards Act 2000* was accompanied by minimum standards set by the Department and minimum standards have continued to be a part of the regulatory system since then.

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[10] The inspection of children's social care services was transferred to Ofsted in April 2007. CSCI regulates domiciliary care for children and young persons and independent specialist colleges.

[11] Tom Burgner, The regulation and Inspection of Social Services, Department of Health and Welsh Office 1996

Social care is currently inspected against National Minimum Standards published by the Department of Health under the *Care Standards Act 2000.* The standards set a minimum level of service for each element of a care service. Compliance with national minimum standards is not directly enforceable but CSCI takes the national minimum standards into account when assessing a care provider's compliance with mandatory service-specific Regulations. The standards are available on the Department of Health website.[12]

Following an inspection CSCI will publish an inspection report on the quality of the social care service and may suggest areas for improvement. CSCI can require a care provider to produce an improvement plan setting out how they will improve and their timetable for doing so. In cases where there has been a breach of service regulations by a care provider, CSCI can issue a formal caution, impose conditions on registration or deregister a provider. CSCI can also prosecute the registered provider of a service in cases where it believes an offence has been committed.

The Bill's Impact Assessment describes the duties and powers of CSCI as follows:

- CSCI registers all providers (public and independent sector) and has the power to de-register them if they fail to comply with Regulations.
- Registration of providers takes place at the level of establishment or agency.
- The regulations additionally require the registration of managers of establishments/agencies in addition to the registered person. Their registration is not transferable.
- CSCI is obliged to inspect providers at least once every three years regardless of any identified risks (though more frequent inspections may be made if risks are identified).
- CSCI's set of sanctions to tackle breaches of Regulations by registered providers is limited to simple cautions, conditions on registration, and deregistration. It can also prosecute responsible managers, and/or the "registered person" (an individual, partnership or company).

3. Healthcare Commission (Commission for Healthcare Audit and Inspection) (CHAI)

The Healthcare Commission was set up in April 2004 under the *Health and Social Care (Community Health and Standards) Act*. Like CSCI (see above), it arose from the merger of the functions of several organisations: the Commission for Health Improvement (CHI), which was abolished, the health value for money work of the Audit Commission (but not its auditing functions); and the independent healthcare sector work of the National Care Standards Commission, which was abolished by the Act.

The history of social services regulation (see above) though largely separate from the development of healthcare regulation, does overlap in relation to independent hospitals.

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[12] http://www.dh.gov.uk/en/Policyandguidance/SocialCare/Standardsandregulation/DH_079561

These were covered by the *Registered Homes Act 1984* to the extent that they fell within the definition of a nursing home.

The *Care Standards Act 2000*, which repealed the 1984 Act and blurred the distinction between nursing homes and residential homes, also separated off the independent sector hospitals, to be registered and inspected as a separate category with the Care Standards Commission. Their regulation was still separate from regulation of the NHS, which was undertaken by a separate body (CHI). Indeed, at the time that the *Care Standards Act 2000* was making its way through Parliament the question whether the NHS and the independent sector were so different in character that they should be regulated in different ways was the subject of considerable debate. The Government's argument at the time was that they should be kept separate. [13]

The Commission of Health Inspection (CHI), which the Healthcare Commission also replaced, was set up under the *Health Act 1999* and started operating in April 2000. CHI had been part of a set of "quality improvement" measures contained in the Act, including among them a requirement for NHS bodies to be subject to a general duty of quality. In the NHS Plan published by the Government in 2000 the Government explained how much of an innovation it considered an independent inspectorate for the NHS (CHI) to be. It was given more power and greater independence by the *NHS and Healthcare Professions Act 2002* though it was in practice soon replaced by the Healthcare Commission. The NHS Plan said:

> The NHS, like other public services, needs to be subject to independent scrutiny. Local people have the right to know how effective their local health services are. In addition inspection helps identify all that is good about an organisation as well as highlighting problems that need to be addressed. But until the Government set up the Commission for Health Improvement the NHS lacked any independent inspectorate. Commission for Health Improvement will quality-assure the care of NHS hospitals as well as community and primary care services. [The NHS Plan 2000 cm 4848, July 2000 paragraph 6.20]

When the Healthcare Commission was formed in 2004, it took on the functions of the Care Standards Commission towards independent sector hospitals as well as functions relating to the NHS, thus combining for the first time the inspection of public and private healthcare in a single body. However, although the Healthcare Commission has been responsible for regulating both sectors, they are not treated in the same way. For example, NHS bodies do not have to be registered whereas independent sector hospitals do.

The Healthcare Commission's current powers and duties are summarised in the Impact Assessment, as set out below:

- NHS providers are currently assessed through the annual "health check" but are not subject to a formal registration process.

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[13] Library Research Paper 00/52 http://www.parliament.uk/commons/lib/research/rp2000/rp00-052.pdf

- Independent sector (IS) and third-sector providers, which have to register with HC and comply with Regulations under the Care Standards Act 2000, are assessed against national minimum standards.
- Registration of IS providers takes place at the level of establishment or agency.
- The regulations additionally require the registration of managers of establishments/agencies in addition to the "registered person" (an individual, partnership or company). Their registration is not transferable
- The regulator is obliged to inspect IS providers at least once every five years regardless of any identified risks (though more frequent inspections may be made if risks are identified).
- In the case of service failure, only the Secretary of State has enforcement powers in relation to NHS providers (in the case of Foundation Trusts, Monitor has some of these powers and in the case of health care associated infection, the HC has a power to issue improvement notices).
- On the other hand, HC has the powers to close IS providers down if they fail to comply with the Regulations linked to continuing registration.
- HC's set of sanctions to tackle breaches of Regulations by registered providers is limited to simple cautions, conditions on registration, and deregistration. It can also prosecute responsible managers and/or the "registered person" (an individual, partnership or company).

B. The Bill: background, content and responses

1. Background

The Healthcare Commission and the Commission for Social Care Inspection (CSCI) were left untouched in July 2004 when the results of the Department of Health's review of arm's length bodies were announced. There was a reference to the "direction of travel" being towards "combined health and social care inspection" but the report said that any merger between CSCI and the Healthcare Commission at that time would be "a distraction from the heavy agenda of both sides and would impact on the ability of both to regulate providers and thereby protect patients and service users".[14]

The announcement of a merger between CSCI and the Healthcare Commission came in Gordon Brown's Budget speech of 16 March 2005 in the context of reducing burdens on business:

> And in addition to reducing inspection bodies from 35 to just nine I can also announce a further reduction. We are today bringing forward proposals for a reduction in public sector inspectorates from 11 to 4 – with single inspectorates for criminal justice, for education and children's services, for social care and health, and for local services.

[14] Department of Health, *Reconfiguring the Department of Health's Arms Length Bodies*, July 2004 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086081

In November 2006, the Department of Health published as a consultation document the *Future Regulation of Health and Social Care* [15] together with an independent study it had commissioned a few months earlier, designed to provide the evidence base for the consultation document.[16] These publications, together with the Bill's Impact Assessment, provide a good deal of discussion about the role of regulation in relation to health and social care, the extent to which it is equivalent to parallel regulation in other spheres, and the driving forces for the proposed changes, in particular the marketisation of services (further developed in social care than in health), Government policies to increase joint working between health and social care, and its policies to deliver services in new ways such as the move from secondary to primary care.[17]

The report of the independent study drew on lessons from other sectors (telecoms, mail and rail) and from other health and social care systems (Australia, Germany, the Netherlands, Norway and Singapore) to describe the regulatory functions needed to ensure the effective operation of these systems. It then proposed options for the future regulatory architecture for health and social care and assessed the pros and cons of each.

The consultation document confirmed the commitment to merge the three organisations responsible for regulating healthcare, adult social care and the operation of the Mental Health Act. It was the first document to describe in any detail the Government's proposals for reform. It also set out some of the arguments for and against various options. The consultation closed in February 2007.

The Draft Legislative Programme announced by the Prime Minister in July 2007 included a Health and Social Care Bill, which among other things, would include a new integrated regulator for health and adult social care. At that stage the proposal was to call it "Ofcare". The proposed name has since changed and the integrated regulator proposed by the Bill would be called the "Care Quality Commission".

The Draft Legislative Programme said that the new regulator would "operate at a significantly lower budget than the existing bodies". A detailed assessment of the costs, including uncertainties about future costs, of the proposals in the Bill is contained in the Impact Assessment. This points to the major policy developments, including cost reductions which are taken as givens in the assessments that it makes:

> 8. All options have to take account of three important policy developments, which are independent of the Bill:
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> - Firstly, the 2005 Budget Report announced the Government's intention to assess more fully the scope to reduce expenditure on

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15 http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_063286

16 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063258

17 These are available on the Department of Health's website together with the Department's own response to the consultation at http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSocialCareBill/index.htm

the main public service inspectorates by about a third over the medium term. Plans are being developed to achieve this target by 2008 (compared to a 2004/05 baseline) as applied to HC and CSCI. This budget reduction is therefore taken as a 'given' under each of the options considered. Obviously this budget reduction has implications for the costs of the regulated as well as the regulator, but the anticipated consequential changes in regulatory-related activity cannot be attributed to the current legislation.

- Secondly, in 2008 free choice of provider is being rolled out for routine elective health services. This means that NHS and independent sector providers will be incentivised to attract patients through the quality of their services, since all providers eligible for payment through the national tariff receive a fixed tariff price for elective treatments. Currently both the regulatory system and the payment of services (NHS bodies are paid by tariff while most ISTCs have commissioned contracts) differ significantly between public and independent providers of NHS services.

- Thirdly, the entry of independent sector providers into commissioning- and choice-driven NHS funded services will add a legal dimension to the functions of PCTs and SHAs in this area. To avoid legal challenges they will have to ensure that their dealings (and the dealings of their NHS providers) are consistent with EC law.

2. Content

The Government's response to the consultation on the future regulation of health and social care published by the Department of Health at the end of 2007[18] explains the Government's vision for the Care Quality Commission and the kind of body that the Bill currently before Parliament is intended to set up.

Like the Impact Assessment, the consultation response describes the changing landscape of health and social care. It highlights one major difference from the proposals put forward in the original consultation document, which is that the new regulator will not be given the function of adjudicating over " competition disputes", that is where there are disagreements between providers and commissioners. It is left to Strategic Health Authorities to manage such disputes.

The consultation response also makes clear that the new Commission will not take on the Healthcare Commission's current role in dealing with second stage complaints from individuals:

> 4.10 We do not believe the investigation of complaints from individual patients or users of services sits easily with the functions of a regulatory body. The Care

[18] http://site320.theclubuk.com/en/Consultations/Responsestoconsultations/DH_078227

> Quality Commission will not therefore take on the Healthcare Commission's current role of dealing with second-stage NHS complaints. The Commission for Social Care Inspection does not hold a corresponding responsibility with regard to social care complaints. The Department of Health has undertaken a public consultation* on reform of the health and social care complaints functions. The main proposals are to align the procedures across health and social care, to make those procedures more responsive to the needs of patients and service users, and to ensure that information from complaints leads to improvements in service delivery.
> **Making experiences count: a new approach to responding to complaints – a document for information and comment,* Department of Health, June 2007

On timing, the consultation response says:

> 4.11 Working with the current commissions, we remain committed to establishing the new regulator in 2008, subject to the passage of legislation. We plan that the Care Quality Commission will be established in October 2008 and will take on responsibility for the regulation of health and adult social care in April 2009 – working towards full implementation of the new registration system from April 2010 (see paragraph 3.19). This means the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission will continue to fulfil their current statutory functions until the end of March 2009.

The consultation response also describes several areas where the Government considers that more consultation is needed. For example:

- We will consult on the detail of the Care Quality Commission's registration function i.e. the registration requirements to be adhered to, and the scope of registration (which services, organisations and providers will be covered).(Paras 3.5 and 3.23) The document also says that more information about arrangements for transferring over existing providers will be provided during this consultation (Para 3.17)
- We will consult on how registration could be introduced for primary care providers…(Para 3.10)

The Impact Assessment describes how the Government's proposals compare with the existing system. Its description is set out below. (A clause by clause description of the Bill is contained in the Department of Health's Explanatory Notes.) The description below is taken from the Impact Assessment's Option 2 minus the promoting choice and competition functions, which, as mentioned above, the consultation response has said, will not be one of the new regulator's functions. (References to Option 1 are to the system as it is now.)

The Impact Assessment also points out that in relation to safety and quality assurance, the Bill includes provision for the sanction of more significant fines (up to £50,000) than are currently available, for example, against serious breaches of registration requirements. In addition, in the case of providing services regulated by the Care Quality Commission without the proper registration, extreme cases would be able to be referred to the Crown Court and providers could be subject to an unlimited fine.

Organisational Structure

25. The three existing regulatory Commissions would be dissolved and a single health and adult social care regulator, the Care Quality Commission, established, subject to Parliamentary approval, taking on responsibility for the regulation of health and adult social care in April 2009 – working towards full implementation of the new registration system from April 2010.

Regulatory Functions

26. The main changes in this option in comparison with option 1 are additional and revised functions for regulating bodies (regulator, PCTs and SHAs) mostly relating to competition and commissioner supervision of health services and the streamlining of different quality assurance checks in health care.

Safety and quality assurance

27. Generally, the two safety and quality assurance systems embedded in the regulation of health and social care would become aligned and streamlined to decrease the burden on providers of both health and adult social care and avoid any duplication of regulatory activity.

28. The coverage of regulation and the safety/quality requirements they are expected to meet (and with that the costs and benefits of this) would be decided in secondary legislation and in the operational methodologies of the regulator. While it would be for the Care Quality Commission to develop and consult on its own models, the intention would be to enable the Care Quality Commission to assess risk and take proportionate action across health and adult social care, while recognising the significant differences between provision in the two sectors.

29. Safety and quality assurance in health and social care will become more similar in the future system and it is therefore described in one section here.

30. The main changes to the regulatory quality assurance model compared to option 1 are:

- There would be a common registration system for all providers (adult social care, IS and third sector, and NHS health care). Initially all providers currently registered and current NHS providers would be automatically registered, unless they were under current enforcement action. Subsequently, all providers would have to demonstrate ongoing compliance with registration requirements in order to stay registered. The costs and benefits of a single system would greatly depend on the scope of the registration system and the registration requirements, which would be set out in secondary legislation. Secondary legislation would aim at reducing burdens for all providers without loss of safety and quality by facilitating the work of the new regulator to introduce more risk based and proportionate registration.
- The Care Quality Commission would be responsible for identifying breaches of registration requirements by all registered providers, and ensuring they take action to remedy these. As a last resort, it could close down all types of registered providers if they failed to meet these requirements.

- The Care Quality Commission would receive additional powers to sanction registered providers (e.g. fines, warning notices and temporary suspensions) if it found registration requirements had been breached.
- Providers would be able to submit a single application covering all their registerable service provision. While secondary legislation would set out which types of service provision needed to be covered by registration, the basic unit of registration with the Care Quality Commission, in administrative terms, would effectively be at the organisation level (company or charity or trust), so that the regulator would operate parts of the registration process (governance processes such as HR policies) at that level to avoid duplication, rather than for each service location or individual provider unit.
- The requirement to have a registered manager in particular cases would be included as a condition of registration for specific types of care provision, and release providers with suitable quality assurance systems from the duty of naming a registered manager at each registered location.
- The Care Quality Commission would take on new 'gatekeeping' functions that would go beyond the current non-binding concordat. These would be designed to minimise the burden of inspection on front line public services. Specified public authorities that wanted to request data and/or wanted to inspect a provider would have to consult the regulator first as to whether similar data was already available or if inspection dates could be coordinated.
- There would be no minimum inspection frequency, and the Care Quality Commission would decide the frequency independently, taking into account the key principles of better regulation.

31. *Monitoring the Mental Health Act 1983 and other related statutory functions:*

- The Care Quality Commission would undertake to visit with individual patients in England who are subject to compulsion; either detained in NHS and independent hospitals or subject to Community Treatment Orders or Guardianship Orders under the Mental Health Act 1983. Patient interviews would be in private and record checks would confirm compliance with the Mental Health Act and its Code of Practice.
- The Care Quality Commission would have a power to investigate issues related to the use of the Act's powers regarding patients subject to compulsion as requested by patients, third parties or of its own volition.
- Wherever a Care Quality Commission provider report directed recommendations at providers who exercised the powers of the Act such providers would be required to publish the action they took in response. The Care Quality Commission would be empowered to provide advice to the Secretary of State on the operation of the Act.
- The Care Quality Commission would have access to comprehensive statistical information on the use of the Act's provisions.
- The Care Quality Commission would receive notifications on the death of any patient subject to compulsion.
- The Care Quality Commission would be required to publish an annual rather than biennial report, on its activities in keeping under review the operation of the Act, which would be laid before Parliament.

Promoting choice and competition (paragraphs 32 and 33 not included as this proposals has been dropped)

Commissioner assurance

34. Health care: As in option 1, the 10 SHAs would be responsible for the performance management of commissioners and the regulator would undertake an assessment of PCTs' performance as commissioners. In contrast to option 1, DH would develop the measures and indicators for this assessment in order to help focus commissioning on patients' needs. The responsibility to act on the results of the performance assessment reviews would remain with SHAs. The frequency of the reviews would not be fixed as annual, but be determined by the Care Quality Commission and approved by the Secretary of State.

35. In undertaking this function the Care Quality Commission would need to work closely with the Audit Commission, which would continue to carry out the annual audit of commissioners' accounts and reporting on their financial statements including whether there were proper arrangements for securing economy, efficiency and effectiveness in the use of resources.

36. Social care: In contrast to option 1, the DH would develop the measures and indicators for these reviews focused on outcomes for, and the experience of, people who use adult social care services. The frequency of the reviews would not be fixed at annual, but be determined by the Care Quality Commission and approved by the Secretary of State.

37. From April 2009, there will be a new lighter touch risk-triggered inspection and audit regime for local government. Inspection will be mainly based on a joint risk assessment carried out by all inspectorates. The current comprehensive performance assessment (CPA) will be replaced by a comprehensive area assessment (CAA). Government departments have jointly commissioned the Audit Commission to take work on the CAA forward.

Information and performance review of providers

38. Health care: In addition to the information required for the registration system, the Care Quality Commission would analyse and publish data for performance review purposes for NHS bodies. It would assess a body's performance by reference to such indicators of quality as the Secretary of State may devise or approve. It would provide a performance rating for NHS bodies. The expectation would be that secondary legislation would be introduced to allow the Care Quality Commission to performance assess independent providers of NHS health care. The assessment could be extended, through secondary legislation, to cover other health care providers, but this would be explored in a later stage impact assessment. They will also be able to carry out thematic reviews or special studies.

39. Social care: Additionally to the information required for the registration system, the regulator would analyse and publish data for performance assessment purposes for all adult social care providers that provide LA funded care. It would assess a body's performance by reference to such indicators of quality as the Secretary of State may devise or approve. The expectation would be that secondary legislation would be introduced to allow the Care Quality Commission to performance assess and rate providers of both LA- and privately-funded adult social care. They will also be able to carry out thematic reviews or special studies.

3. Responses

Many of the responses to the consultation document issued by the Department of Health in November 2006 on the future regulation of health and social care are available on the Department of Health's website with the consultation document. As the reforms proposed have changed little since then (apart from the removal of the new regulator's proposed appeal function over commissioning decision), most of these are still relevant.[19]

Recent newspaper articles that comment on the proposed new Commission include:

- Guardian Society Interview Sir Ian Kennedy, 17 October 2007
- Sleepwalking into an unhealthy alliance, the Guardian 14 November 2007

At the time of writing many organizations are still finalizing their responses to the Bill. Some of the issues relating to the new regulator were raised in the debate on the Queen's Speech, particularly the impact on social care, which was raised several times during the debate in the House of Lords on 8 November 2007. Many of the points raised are quoted in the briefing on the Bill produced by the Commission for Social Care Inspection (CSCI). CSCI's own views are summarized below and are available in more detail in the briefing, which is available on its website.[20]:

Commission for Social Care Inspection

> ***The New Body Should Retain a Strong Social Care Focus***
>
> While there are good arguments that health and social care should become more closely integrated we have strong concerns that such a "marrying up" is done in a way that avoids health dominating and becoming the main focus of the new body.
>
> For example, there are concerns that additional duties for the Care Quality Commission unless they are separately and adequately funded (such as any stemming from the current focus on the cleanliness of hospitals), will cause already tight resources to move from the social care to the health side.
>
> ***The New Body Should Build on Existing Progress***
>
> We believe the bill should ensure that not only all CSCI's current powers are taken forward, but also that the positive work that CSCI has carried out over the last three years is protected. We want to ensure that the 2003 Act is built upon in the light of CSCI's experience. Simply carrying over the powers outlined in

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19 See the links to respondents at http://site320.theclubuk.com/en/Consultations/Responsestoconsultations/DH_078227

20 http://www.csci.org.uk/

CSCI's enabling Act may not be enough to do so, especially if the new body is perceived to be dominated by health issues.

It may be that the best way of doing this is to ensure that the structure of the new Commission is such that it represents people with both health and social care interests

The New Body Should Take a "Rights Based Approach"

CSCI believes, in line with general government policy, that the new regulator should take a strong rights based approach towards the people who use health and social care services. The new Commission should place the rights of the people who use services and their carers at the heart of its work and they should have clear rights of access to it. We would want to ensure that this approach is reflected throughout the legislation.

The New Body Should Retain Independence

The bill delegates many matters to secondary legislation. The current arrangements with the Department of Health work well. DH is CSCI's sponsor department and are accountable to Parliament for our work as well as agreeing our annual budget with us. However, we want to ensure that the new body still remains an independent regulator rather than become an "arms length" body with many of the decisions about how it operates being made directly by Ministers through regulation (which will not receive the same level of Parliamentary scrutiny).

Mental Health Act Commission

A press notice issued by the Mental Health Act Commission on 24 October 2007 said:

Regular visits by an independent body with the appropriate expertise are a vital safeguard for people who are mentally ill and are detained under the powers of the Mental Health Act. Detention or compulsory deprivation of liberty is a very serious matter and can place a person in a very vulnerable situation. We are please that the Government has recognized this in its plans for the future regulation of health and adult social care.

No organisation wishes for its own abolition! The Mental Health Commission is concerned that with the merger of its functions into a large regulatory body with a wide variety of functions that monitoring of the operation of the Mental Health Act and the protection of vulnerable patients may not get the priority it needs. However, MHAC recognizes also that there are advantages as well as possible disadvantages in the establishment of the Care Quality Commission, such as the availability of enforcement powers and sanctions against hospital which fail to comply with the law. These will provide the new regulator with much sharper "teeth" than any of its predecessor organizations……

…. Speaking today, Chris Heginbotham, Chief Executive of the Mental Health Act Commission, said, "We accept the need to strengthen regulation of health and social care, but we want to be sure that the rights of detained patients are protected and that the new regulator will devote sufficient resource to continuing the essential visiting programme undertaken by MHAC. Only by visiting detained patients regularly and frequently can abuses be identified and rooted out."

The Healthcare Commission

On 25 October 2007, after publication of the Government's response to the consultation on the future of health and social care regulation, the Healthcare Commission issued a press notice, which said:

> Commenting on the Department of Health's vision for the regulation of health and social care, published today (Wednesday), the Chairman of the Healthcare Commission Sir Ian Kennedy said:
>
> "It was very encouraging to hear the Prime Minister recognise the importance of independent regulation when he expressed a desire for 'a stronger healthcare commission' in his speech to the Labour Party conference a few weeks ago.
>
> "The vision set out by the Department offers a sound basis for the regulators' functions. It means that the regulator would have additional powers while continuing to maintain a modern, risk-based information-driven approach to regulation.
>
> "Caution, however, needs to be exercised. A regulator should not go around the NHS closing places down. Rather, its primary role should be to ensure that the boards of trusts safeguard the interests of patients. Even when things go wrong, it should ordinarily confine itself to making recommendations for others on the spot to manage, save in the last resort.
>
> "It is important that the proposed approach, based on registration, is evolutionary. It needs to build on the progress that the NHS and the independent sector have made towards meeting the government's current set of standards for performance."
>
> On specific matters, Sir Ian welcomed the government's response to the Commission's advice during the consultation process.
>
> He said: "We emphasised to the government the importance of including an independent assessment of how primary care trusts commission care on behalf of the communities they serve.
>
> "This is essential so as to hold to account those responsible for spending so much of the NHS budget. Otherwise, the public would have no independent view on whether they were doing a good job.
>
> "We also stressed the importance of the regulators retaining the power to initiate a review of areas of care without needing approval from the Secretary of State.
>
> "An independent regulator needs the freedom to check on matters or services where patients have concerns. We, for example, have commissioned national reviews on maternity care, learning disability services and the dignity of care in hospital. Moreover, reviews are crucial in assessing how well patients are cared for as they are looked after at various stages."
>
> Sir Ian added: "We all know that restructuring organisations involves distraction, delay and cost. With the vision for the regulator broadly right, I would urge the government to do more to articulate to patients and the public the benefits of

creating the new organisation and abolishing the existing ones. We have to be ready for the challenge of building something new, while at the same time not losing momentum.

"I strongly welcome the desire of current Ministers to use regulation to meet their objectives. I am anxious that we get on with the things that matter most to patients, rather than wait for new legislation. We have plenty of powers already. We have used them and will continue to do so in the interests of patients.

"In this way, we can meet the challenge reflected in the Prime Minister's call for action by the Healthcare Commission, particularly in the realm of safety."[21]

Local Government Association: extract from its briefing on the Bill

On balance, the creation of a single regulator is a positive step. However, it is essential that the CQC works appropriately with the new Comprehensive Area Assessment process; it should not lead to the duplication or unnecessary creation of inspection regimes

The CQC must support councils in achieving their ambitions for local communities. It should not impose its own vision on places. Consideration must also be given to how the three-way relationship between the CQC, councils and NHS providers will be developed and managed in areas of joint provision.[22]

III Regulation of health professions and health and social care workforce

(Part 2 clauses 91-118 and schedules 6-10)

A. Territorial extent

This part of the Bill mostly relates to the UK as the regulation of most healthcare professions is reserved to Westminster. However, for some professions this is devolved to the Scottish Parliament, which will have responsibility for newly regulated professions in the future. A Legislative Consent Motion is needed for those aspects of the Bill's provisions that legislate in respect of devolved matters.

The Bill's Explanatory Notes say that legislation extends to Northern Ireland by consent.

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21 http://www.healthcarecommission.org.uk//newsandevents/pressreleases.cfm?cit_id=5898&FAArea1=customWidgets.content_view_1&usecache=false

22 http://www.lga.gov.uk/Documents/Briefing/Health_and_Social_Care_Bill%20-%20LGA%20Briefing191107.pdf

Provisions for the regulation of the social care workforce extend to England and Wales only, as does the duty to be imposed on healthcare organisations to co-operate.

Although provisions about conferring functions on responsible officers applies to the UK, the provision enabling certain additional functions to be conferred on them does not apply to Scotland.

B. Background

The Labour Party's 2005 General Election Manifesto undertook to strengthen the clinical accountability of professionals:

> In the light of the findings of the Shipman Inquiry, we will strengthen clinical governance in the NHS to ensure that professional activity is fully accountable to patients, their families and the wider public.

The commitment followed a number of high profile inquiries into doctors who had harmed their patients, notably the Shipman, Kerr-Haslam, Ayling and Neale Inquiries.[23] Of these, the Shipman Inquiry was probably the one to attract most general attention and it undoubtedly included severe criticisms of the system of professional regulation.

In her letter to Health and Home Office Ministers on her Fifth Report of the Shipman Enquiry,[24] Dame Janet Smith, who chaired the inquiry, included the following comments about the General Medical Council, the body that registers and regulates doctors:

> Although I do not think that the GMC should be criticised for its rehabilitative approach to cases of drug abuse, I have criticised it because, within the framework of that approach, its procedures focussed too much on the interests of the doctors and not sufficiently on the protection of patients…[25]

In July 2006, the Department of Health published a report on medical regulation by the *Chief Medical Officer, Good Doctors, Safer Patients* [26] and one on *The regulation of the non-medical healthcare professions*[27] . Following consultation, which closed in November 2006, the Department published a White Paper in February 2007, *Trust Assurance and Safety: the Regulation of Health Professionals in the 21st Century*, Cm 7013, setting out its plans for the reform of professional regulation. [28] On the same day the Government

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23 These are cited in the Chief Medical Officer's Report referred to below. The Bill's EN also includes a long list of references to relevant inquiries.

24 Fifth Report - Safeguarding Patients: Lessons from the Past - Proposals for the Future, Published 9 December 2004, Command Paper Cm 6394: http://www.the-shipman-inquiry.org.uk/fifthreport.asp

25 Letter dated November 2004, available on the website of the Shipman Inquiry http://www.the-shipman-inquiry.org.uk/fifthreport.asp

26 http://site320.theclubuk.com/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232

27 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137239

28 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

also published its response to the Fifth Report of the Shipman Inquiry, *Safeguarding Patients*,[29] which also addressed some of the recommendations of the inquiries into the conduct of Richard Neale, Clifford Ayling, Michael Haslam and William Kerr.

The proposals for change need to be understood against the background of the present system, which is often referred to as a self-regulatory one, not because there is no statutory provision, but because the professions have sometimes been considered to dominate their respective regulatory bodies. (See, for example, the quote from the letter by Dame Janet Smith reproduced above.)

There is a statutory regulatory framework for each of the healthcare professions and for the social care workforce. These are listed below. Their titles are largely self-explanatory except for the Health Professions Council, which is responsible for a range of professionals such as physiotherapists, chiropodists, speech therapists etc.

- General Chiropractic Council
- General Dental Council
- General Medical Council
- General Optical Council
- General Osteopathic Council
- Health Professions Council
- Nursing and Midwifery Council
- Pharmaceutical Society of Northern Ireland
- Royal Pharmaceutical Society of Great Britain

In addition, a Council for the Regulation of Health Care Professionals (known in practice as the Council for Healthcare Regulatory Excellence) was set up under the *National Health Service Reform and Health Care Professions Act 2002* as an overarching body promoting best practice and consistency throughout the UK by all the regulatory bodies listed above. It has the power to review the performance of regulators and to refer cases of "undue leniency" to court.

29 http://www.dh.gov.uk/en/Policyandguidance/Humanresourcesandtraining/Modernisingprofessionalregulation/DH_066025

The Bill's provisions would affect in various ways all of these bodies and also the General Social Care Council, which regulates social work and the Care Council for Wales, which regulates social workers in Wales. (Regulation of the social care work force is separate in Scotland.)

C. Measures in the Bill

This Section provides a summary of measures in Part 2 of the Bill accompanied by background information drawn from several sources, including the Bill's Explanatory Notes and the Impact Assessment. The Explanatory Notes also provide a clause by clause description, which this Paper does not repeat. The following description provides a broad outline only. More detailed points are made in some of the briefings received which are quoted in this Paper. Provision is made for:

The creation of an independent adjudicator: The Office of the Health Professions Adjudicator: This would be a new body, It would take over fitness to practise cases from the General Medical Council (in relation to doctors) and the General Optical Council (in relation to opticians). This measure is designed to fulfil the objective set out in the White Paper, that the adjudication of fitness to practise cases should be separated from their investigation and prosecution. The right of appeal to a court in "too lenient" cases, which the Council for Healthcare Regulatory Excellence now has in relation to the adjudication decisions of these councils, would be transferred to the councils, who would no longer be adjudicating on the cases themselves.

Imposing the civil standard of proof in fitness to practise *cases* on those healthcare regulators who do not currently use it. The criminal standard requires guilt to be established beyond reasonable doubt; the civil standard only requires guilt to be established on the balance of probabilities. Currently only three regulators, the General Medical Council, the General Optical council and the Nursing and Midwifery Council still use the criminal standard. Provision is made in the Bill for use of the civil standard in any proceedings that relate to a social care worker's suitability to be or remain registered. The aim is to provide a consistent standard across all the health and social care regulators.

Removing the restriction on lay majorities on the councils of regulatory bodies: This would enable the councils of regulatory bodies to have a lay majority on their council, should they wish to do so. All councils would have to have as a minimum parity between lay and professional members but would not be required to have a lay majority.

Extending section 60 of the Health Act 1999 to allow changes to the regulation of pharmacy: The measure in the Bill would allow the removal of the regulatory functions of the Royal Pharmaceutical Society of Great Britain and allow them to be transferred to a new regulatory body. The new regulatory body would be created through an Order under Section 60 of the *Health Act 1999*. At the moment the regulation of pharmacy is shared by two bodies, one for Great Britain and one for Northern Ireland, which differ from each other. The GB body covers professional regulation as well as representation of the profession. It also has a role in regulating and inspecting pharmacy premises. The Government considers that this dual role creates a potential conflict of interest and has said that it intends to create a new General Pharmaceutical Council. The Explanatory

Notes say that the intention is for this to include Northern Ireland, subject to a decision by Northern Ireland Ministers.

Changes to the Council for Healthcare Regulatory Excellence: The Council would be officially renamed. Its statutory name is the Council for the Regulation of Healthcare Professionals (under the *NHS Reform and Healthcare Professions Act*, which established it) but it currently already calls itself the Council for Healthcare Regulatory Excellence. The Bill also makes provision to change the Council's functions and governance arrangements, for example, the chair and non-executives would be appointed by Ministers, who would be able to devolve the appointments to the Appointments Commission.

The creation of "Responsible Officers": The Bill would provide for regulations to require designated bodies (those providing healthcare or contracting with doctors) in the UK to nominate or appoint "responsible officers" who would have statutory duties in relation to the medical profession, for example, to consider whether concerns about fitness to practise cases should be referred to General Medical Council.

The extension of the role of "Responsible Officers" in England and Wales to clinical governance issues, in particular the monitoring of conduct and performance of doctors, through regulations.

A duty of collaboration: Healthcare organisations and other specified bodies in England and Wales would have a duty to collaborate in sharing information about healthcare professionals whose performance or conduct gave rise to concern, and to agree action to protect patients and the public.

Power to allow changes to the regulation of social care workers and changes to the functions of the General Social Care Council and Care Council for Wales through regulations. Section 60 of the *Health Act 1999* currently allows changes to be made to the regulation of health professionals through secondary legislation. The Explanatory Notes say that the provisions relating to social care workers are intended to mirror the section 60 arrangements.

D. Responses

As mentioned in relation to the responses to the proposals for a Care Quality Commission, at the time of writing many organisations are still preparing their responses to the Bill. A wider range of views than those represented here may be found in the written responses to the consultation documents referred to in the background section above although these are not necessarily focused on the specific provisions in the Bill. [30] As mentioned above, several briefings will be available from the Library even though they are not included in the Paper.

[30] http://www.bma.org.uk/ap.nsf/Content/HealthandSocialCareBill (Briefing on the Bill available just as this Paper was gong to Press)

The most vociferous opposition to proposals in the Bill appears to have come from the British Medical Association, which has issued a number of press notices expressing its disagreement with the proposal to introduce the civil standard of proof. It argues that there is no evidence that changing the standard of proof will protect patients from dangerous or incompetent doctors. In a press notice issued on 30 October 2007, Dr Hamish Meldrum, the BMA's chairman, was quoted saying:

> If a doctor is at risk of losing his or her livelihood then nothing less than the current criminal standard of proof will do and the BMA will do all it can to maintain this. Any restriction on a doctor's ability to practise medicine, even quite limited conditions, can seriously damage their career and often ends their full-time employment and can compromise their position as a trainer. …

In another one, issued on 6 November 2007, in response to the Queen's speech, he said:

> The BMA is keen to ensure that patients are protected from the small minority of doctors who represent a threat to patients. However, this will not be achieved by abandoning the criminal standard of proof. The best protection for the public will be achieved by a system that commands the confidence of the profession and will encourage doctors to speak about problems with their own practice or that of their colleagues. We urge the government to think again.
>
> If a doctor is at risk of losing their livelihood then surely nothing less that the current criminal standard of proof will do. The BMA will continue to lobby very hard to maintain this.

The views of some of the statutory regulatory councils are set below.

General Medical Council, Extract from its Briefing on the Bill: Overview

> The GMC welcomes the publication of the Health and Social Care Bill as a further step towards implementation of the White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century.* The proposals we published in November 2006, which are reflected in the White Paper, provide the basis for a strong, independent and accountable system of health professional regulation into the foreseeable future.
>
> A number of provisions in the Bill relate specifically to the GMC and its work:
>
> - Office of the Health Professions Adjudicator – the GMC is committed to working with the Government to ensure a smooth transition to an independent adjudication body, subject to a satisfactory agreement on the details (Clauses 91-102, Schedules 6-7).
>
> - We welcome the placing of GMC sanctions guidance onto a statutory footing as this reinforces the GMC's ownership of professional standards for the medical profession (Schedule 7).
>
> - We welcome the introduction of a statutory right for the GMC to appeal against decisions of OHPA, reflecting our continuing responsibility for the fitness for purpose of the medical register and the fitness to practise of those on it (Schedule 7).

- The requirement to adopt the civil standard of proof is consistent with the decision the GMC has already taken and with the practice of the majority of other health care regulators (Clause 104).

- Responsible Officers – the GMC welcomes the strengthening of local clinical governance systems. Effective local systems will be vital for the delivery of a robust system of revalidation for doctors (Clauses 110-119).

Council for Healthcare Regulatory Excellence General Briefing on the Health and Social Care Bill

Key messages

- We welcome the implementation of the White Paper *Trust, Assurance and Safety* in the Health and Social Care Bill
- We support proposals to make CHRE an authoritative independent voice for patients in the regulation of health professionals
- We are concerned that the Bill should contain all the necessary clauses to enable CHRE to carry out its new roles and responsibilities.

CHRE comments on these proposals

We welcome the White Paper *Trust, Assurance and Safety*, and specifically:

- The proposal that we should have a smaller Council, with all members independently appointed, which will no longer include members nominated by the regulators. The Government sees CHRE as *'an authoritative independent voice for patients on the regulation of professionals, providing expert advice on policy'*. The composition and appointment of the members on our Council will enable us to be this independent voice on regulation.
- The introduction of the civil standard of proof, flexibly applied, rather than the criminal standard for all regulators. This is consistent with the focus of regulation on the public interest, but keeps the balance right with fairness to registrants.
- The Government's intention to enable revalidation for doctors, as we strongly support the introduction of revalidation for all regulated health professions. The public are entitled to expect that healthcare practitioners remain competent and safe to practise throughout their professional career.
- More independent adjudication of fitness to practise cases across regulatory bodies. The Bill will establish an Independent Adjudicator which will adjudicate on cases about doctors, establish a central list of panellists for the other health professions, and may over time carry out adjudication for other professions. We believe that public protection and confidence in regulation will be enhanced by consistent fitness to practise processes for all professions. We expect the procedures of the new body and those of the other regulators to be harmonised over time.

However, we are concerned that the Bill does not enable some of our new responsibilities proposed by the White Paper. We recommend that:

- The Bill should amend our Act to enable us to carry out the audit of the cases that the regulators have not taken to full fitness to practise panels. We welcome the new power to audit the preliminary stages of the fitness to practise process. However, sub-section 26(3) of our Act currently prevents CHRE doing anything about the case of an individual at the preliminary stages of the fitness to practise process, and therefore would prevent this audit.
- The Bill should enable exchange of information with the new Independent Adjudication Body, to enable CHRE to monitor GMC's appeals of the Independent Body decisions.

IV Part 3 - Public Health Protection

A. Background

Public health policy is concerned with the prevention and control of disease at a population level. Public health measures have been used since ancient times. There is some evidence that the Chinese used a technique called variolation (similar to vaccination) to prevent the spread of smallpox, and Roman cultures certainly had well developed sanitation and waste removal.

The *miasma* (meaning "bad air") theory of disease transmission held for centuries, but began to be superseded by the germ theory in the 19th century. Proof that disease was spread by micro-organisms, which could be transported in a variety of ways, was first provided by Dr John Snow's epidemiological work, and backed up by Louis Pasteur and Robert Koch's microbiological work.

The threat from infectious diseases has changed over time. Diseases that wiped out populations in previous generations have now vanished or been much restricted. By contrast, other diseases, such as SARS and pandemic influenza, have emerged.

Other new threats to public health include chemical, biological, radiological and nuclear weapons, known collectively as CBRN. Governments are increasingly concerned with protecting their citizens from these "new" ways of spreading disease. The inclusion of the CBRN threat, as well as other threats to human health, is the foundation of the "all hazards" approach to public health, espoused by the World Health Organisation (WHO) International Health Regulations (IHR) (2005).[31]

Domestically, modern public health policy has concerned itself with more than just the spread of infectious disease. Governments have become far more involved, often through legislation, with trying to influence aspects of behaviour, such as smoking, eating, drinking and exercise, all of which are thought to have a major effect on public health.

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31 WHO International Health Regulations (IHR) (2005)

33 *Medical Law Review 2006* 14(1):132-143; doi:10.1093/medlaw/fwi038

Both cancer screening and adult literacy programmes are examples of pro-active public health interventions that may show a clear benefit to the individuals involved, but other interventions, such as restrictions on movement, may have no benefit for the individual but be important for preventing the spread of disease through society.

Public health policy can be a legal and philosophical battleground between individual autonomy and the "public good". This makes the framing of legislation difficult, and may result in accusations of government running a "nanny state" and compromising civil liberties.

An article in *Medical Law Review*[33] recently described a Swedish case[34] where enforcement of pubic health legislation had been judged to conflict with the European Convention on Human Rights[35]. In its conclusion, the author wrote:

> Law has the potential to be a very useful tool for the attainment of public health. Bad law, however, can serve to create obstacles to public health. Public health consultants in England and Wales have been cautious in using detention powers, even in cases of serious risk of disease spread by a non-compliant patient, because of lack of clarity of the status of these powers in relation to human rights. *Enhorn* illustrates that similar concerns exist in relation to legislation elsewhere in Europe. There have been many calls for reform of public health legislation in the United Kingdom by academic commentators,[36] public health consultants[37] and in government documents.[38] Public health law has undergone a process of reform in other jurisdictions that had adopted their public health laws from English law,[39] following the SARS scare in 2003.[40] Any doubt as to the implications of the Human Rights Act 1998 for the Public Health Act 1984 must now have been settled by the decision in *Enhorn*. Once again we can only call upon the government to make reform of public health an issue of the highest priority and not to wait for the threat of a new or re-emerging disease in order to pass with haste emergency legislation.

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34 *Enhorn* v. *Sweden* [2005] E.C.H.R. 56529/00, para. 41

35 European Court of Human Rights

36 See *e.g.* A. Harris and R. Martin, *supra*, n. 14, and R. Coker, *supra*, n. 17

37 In *the Mail on Sunday*, 15 May 2005, Dr Philip Monk, a communicable disease specialist in Leicestershire, commenting on a case in which 12 people were thought to have contracted tuberculosis from a person with infectious tuberculosis who had refused treatment, said, 'We cannot adequately protect people from infectious diseases ... ... This case illustrates the failures of the current public health laws to perfection. There is an urgent need to review them.' He made similar comments in *the New Scientist*, 14 May 2005.

38 The Acheson Report, *Public Health in England: The Report of the Committee of Inquiry into the Future Development of the Public Health Function* (HMSO 1988); The Department of Health, *Review of Law on Infectious Disease Control: Consultation Document* (1989); Chief Medical Officer, *On the State of the Public Health: The Annual Report of the Chief Medical Officer for the Year 1997* (Department of Health 1998); Chief Medical Officer, *Getting Ahead of the Curve: A Strategy for Combating Infectious Diseases* (Department of Health 2002).

39 Such as New Zealand and Australia

40 Note that after considerable debate, SARS was not made a notifiable disease under UK legislation, in part because without any quarantine powers, there was little point in bringing SARS under the provisions of the Act

The Government stated its intention to draft the new legislation so that it would clearly comply with relevant human rights legislation in the white paper *Review of parts 2, 5 and 6 of the Public Health (Control of Disease) Act 1984: A consultation* [41].

> Human rights, data protection and medical confidentiality
> 2.14 Increased attention has been given to human rights, data protection and medical confidentiality with the passing of the Human Rights Act 1998 and the Data Protection Acts of 1984 and 1998 and the growing recognition of the need to treat as confidential medical information about named individuals. None of these issues is recognised in specific terms in the Public Health (Control of Disease) Act 1984. That does not in itself mean that the Act compels those responsible for implementing it to act in ways that are contrary to legislation on human rights or data protection; but there is nevertheless a case for reviewing and revising the provisions in the Act in the light of more recent legislation.

1. Provisions in the Bill

The Explanatory Notes set out the Government's purpose in introducing the Bill. Paragraph 27 of the notes says:

> The Public Health (Control of Disease) Act 1984 ('the Public Health Act 1984') consolidates earlier legislation, much of it dating from the 19th century. Many of its assumptions, both about risks and about how society operates, are now out of date. It makes highly detailed provision on some matters (for example, it is a criminal offence to expose a public library book to plague, or to hold a wake over the body of a person who has died of cholera) but does not address other matters that are now of concern, such as contamination by chemicals or radiation. Part 3 of the Bill updates the Public Health Act 1984 to take account of these points.

Regulations amended include *Public Health (Infectious Diseases) Regulations 1988*, *Public Health (Aircraft) and (Ships) Regulations 1979* and *Public Health (International Trains) Regulations 1994*.

The Government explains the intentions behind the legislation on the Department of Health website:[42]

> Public Health Protection Measures
> Most public sector activity in England to treat and prevent infectious disease takes place under the legislation governing the National Health Service. There is no compulsion on people to accept NHS services, but take-up of the services on offer is generally very high.
>
> However, individuals taking care of their own health is not always enough to protect the public health. Sometimes a person who has an infectious disease can put others at risk through his behaviour. Consequently, legislation (which dates

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41 *Review of parts 2, 5 and 6 of the Public Health (Control of Disease) Act 1984*: *A consultation* Department of Health, 28 March 2007

42 Department of Health website:16 November 2007

> back to the 19th century) has long provided that local authorities may take certain actions, and make certain requirements, to protect the public health. In certain circumstances, a justice of the peace may require a person who may be suffering from a specified infectious disease to be medically examined; or a person who is known to be suffering from a specified infectious disease to be removed to, and detained in, hospital. That legislation is now included in Part II of the Public Health (Control of Disease) Act 1984, which also includes other provisions aimed at preventing or controlling the spread of infectious disease (for example, there are duties on doctors to report cases of specified infectious diseases).
>
> Successive Governments have given commitments to review the Act, and the Department of Health published a consultation paper in March 2007 which set out proposals for changes to key parts of the Act.
>
> The Bill provides a comprehensive set of public health measures to help prevent and control the spread of serious diseases caused by infection and contamination. It updates the powers in Part II of the Public Health (Control of Disease Act) 1984 for preventing and controlling the spread of disease, and extends them to cover radioactive or chemical contamination.
>
> Other than the extension to contamination, all the powers are based on the existing powers in the Public Health (Control of Disease Act) 1984.
>
> These powers will provide flexible and proportionate safety measures to ensure that where an individual refuses to take action voluntarily to protect the public from infection or contamination, they can be required to do so, to safeguard public health.

It is widely agreed that the law in this area is in need of updating. In a submission to the House of Lords Select Committee on Science and Technology, in February 2003, the Faculty of Public Health Medicine gave the following statement:

> It has been recognised for some years that public health law is out of date and this was emphasised in *Getting Ahead of the Curve.* For example, it seems anomalous that legal responsibility for communicable disease control is with local authorities whilst most of the staff engaged in this area of work are working in the health sector, due to the failure to revise the legal position with sequential reorganisation of the NHS. Equally, the legal tools available to those responsible for local communicable disease control are considered inadequate when dealing with serious diseases such as multi-drug resistant infectious tuberculosis[43].

2. Consultation prior to this legislation

In March 2007, the Government launched a consultation: *Review of Parts II, V and VI of the Public Health (Control of Disease) Act 1984.*[44] The consultation closed on 25 June 2007, and the report on the consultation[45] was published around the same time as the

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43 Sub-Committee I Fighting Infection HL Select Committee on Science and Technology, 18 February 2003

44 Review of parts 2, 5 and 6 of the Public Health (Control of Disease) Act 1984: A consultation, 28 March 2007

45 Review of Parts II, V and VI of the Public Health (Control of Disease) Act 1984: report on consultation, 15 November 2007

Health and Social Care Bill. There was unanimous agreement from respondents that the law in this area was in need of up dating.

B. Clause 119

Part 3 of the Bill contains provisions amending the *Public Health (Control of Disease) Act 1984*. Clause 119 would introduce a new Part 2A, with new sections 45A -S, into the 1984 Act.

1. New section 45A definitions

Some definitions and terms have been changed from previous legislation: conveyances is used to describe ships aeroplanes, trains and any other vehicle, superseding the separate regulations for air, ships and international trains, and avoiding any confusion about applicability to other craft. Use of the word "contamination" specifically includes radiation, and the use of the word "thing" includes (but is not restricted to) human tissue, remains, animal and plant material. References to decontamination and disinfection include the removal of any vector, agent or source; the definition used in this legislation lacks the specificity of technical definitions of disinfection and decontamination normally used by health professionals.

2. Ministerial Powers

a. 45B - Ministerial Powers to incorporate international treaties into UK law

This new section gives the appropriate minister regulation making powers to enshrine the WHO international Health Regulations (IHR)(2005)[46] into British law. These regulations came into effect in June 2007. Most of the provisions of these regulations are already well established in the UK, but new section 45B gives the appropriate minister power to update UK law without recourse to Parliament if or when there may be amendments or developments to them. The WHO website describes the main features of the regulations:

> **Notification**
> The IHR (2005) require States to notify WHO of all events that may constitute a public health emergency of international concern and to respond to requests for verification of information regarding such events. This will enable WHO to ensure appropriate technical collaboration for effective prevention of such emergencies or containment of outbreaks and, under certain defined circumstances, inform other States of the public health risks where action is necessary on their part.
>
> The new notification requirements, together with WHO's mandate to seek verification of unofficial reports of events with potential international implications, and the establishment of National IHR Focal Points, is intended to promote and facilitate information sharing between WHO and its Member States. Greater understanding of the event as it unfolds, plus the assurance of timely technical

[46] WHO International Health Regulations (IHR) (2005)

collaboration, is expected to lead to a climate of greater willingness on the part of Member States to contact the WHO when a possible public health emergency of international concern is suspected.

National IHR Focal Points and WHO IHR Contact Points
Important innovations under the IHR (2005) are the requirements that notification and reporting by States Parties, as well as other urgent IHR communications, are transmitted through specific National IHR Focal Points to WHO IHR Contact Points, available on a 24 hour-a-day basis, seven days a week.

Requirements for national core capacities
A fundamental innovation in the IHR (2005) is the requirement that each country develop, strengthen and maintain core public health capacities for surveillance and response by using existing national resources, such as the national plans for influenza pandemic preparedness. Key sanitary and health services and facilities are also to be developed at international airports, ports and ground crossings designated for this purpose by States Parties.

Recommended measures
WHO's response to a public health emergency of international concern will include temporary recommendations concerning appropriate public health responses, and may include recommended measures for application by the State affected by such an emergency, as well as by other States and by operators of international transport. These temporary recommendations are made by WHO on a time-limited, risk-specific basis, as a result of a public health emergency of international concern.

Standing recommendations indicate the appropriate measures for routine application for specific ongoing public health risks, and are for routine or periodic application. Recommended measures could be directed towards persons, baggage, cargo, containers, ships, aircraft, road vehicles, goods or postal parcels.

External advice regarding the IHR (2005)
The IHR (2005) include procedures for obtaining independent technical advice concerning IHR implementation. One context is the process for the establishment of an Emergency Committee to advise the Director-General of WHO in determining whether a particular event is, in fact, a public health emergency of international concern and to provide advice on any appropriate temporary recommendations. An IHR Review Committee is tasked with advising the Director-General on technical matters relating to standing recommendations, the functioning of the Regulations and amendments thereto.

A recent article in *Lloyd's List* describes the difficulties in managing disease outbreaks at ports, and highlights the fact that the WHO has no sanctions associated with the regulations[47]:

Ports ill prepared for pandemic outbreaks.

[47] Peter O'Neil, Ports ill prepared for pandemic outbreaks, *Lloyd's List*, 6 November 2007, page 20

> ……When the fear of Sars hit global hubs such as Hong Kong, people deserted offices, quaysides, restaurants, shops, markets and air, rail, bus and ferry services.
>
> There was massive culling of poultry across the region, which affected shipments for the international reefer trade. Fresh and frozen seafood companies in Australia, shipping to deluxe outlets in Asia by air and sea, nearly went bankrupt — consumers stayed at home, sales collapsed and shipments were cancelled.
>
> Shippers move poultry north to south and east to west and vice versa. Less than four weeks ago, CBC reported China following the US and Japan in banning Canadian poultry after H7N3, rather than the human-linked H5N1, was confirmed at a Saskatchewan farm.
>
> The question now is whether there is enough practical advice and guidance out for those on the ground. Port health staff are usually tiny in number and overwhelmed by volume. London's Heathrow airport comes under the domain of the local town council, for example, and Lloyd's List understands that practical information from international organisations has been disturbingly patchy.
>
> But should air and sea port managers be included directly in the global early alert system?
>
> At the moment the International Health Regulations proffered, not enforced, by WHO leave it to governments to set up their own focal point. It is precisely the inability of doctors and directors on the ground to communicate and act preventively, independently and directly that Justice Archie Campbell of Canada attacked a year ago in his investigation into the Sars crisis in Toronto.
>
> Campbell castigated the lack of preparedness and poor communication, and unions will certainly look at his recommendations on training and protecting frontline staff at all ports when it comes to compensation after future events.
>
> Chinese ports and airports seem to be far more geared up in practical terms than their European counterparts and get good marks from their envious peers at international safety seminars.
>
> Lloyd's List has seen thermal scanners operating around the Pearl Delta that pick up higher than healthy temperatures on passenger faces, as people make their way towards exits at ferry terminals.
>
> The fact is, most of the international organisations 'say' rather than 'do' — they leave action to national and local government.
> (…)
> Small ports and provincial international ports should waste no time checking out and tapping their limited resources. Sod's law suggests it will be through these less-well served points that new and old viral threats such as Ebola or legionnaire's will make their international journey.

In the IHR (2005) smallpox, poliomyelitis due to wild-type poliovirus, human influenza caused by a new subtype and Severe Acute Respiratory Syndrome (SARS) become diseases that are immediately notifiable direct to the WHO, whereas cholera, pneumonic plague, yellow fever, viral haemorrhagic fevers and other diseases only need to be

reported if criteria relating to international effects, such as migration and commerce, are met.[48]

New section 45Q allows for the appropriate minister to make regulations relating to international treaties as statutory instruments which can normally go through Parliament under the negative resolution procedure. The only exception, when the affirmative procedure will be used, is if the regulations require amendment to primary legislation.

b. 45C - Ministerial powers make regulations to stop the spread of disease in England and Wales

This new section would allow regulations to be passed that prohibit gatherings and events and compel doctors to notify the authorities of cases of disease or contamination (amongst other provisions). These regulation making powers could be considered fairly wide reaching and potentially draconian, but new section 45D contains a series of provisions aimed at ensuring new section 45C is not abused. These include ensuring the regulations are proportionate and relate to a serious or imminent threat.

The powers to enforce measures such as medical examination or quarantine are only available to JPs, not ministers and are described in new section 45G(2)a-d.

As a further safeguard, new section 45Q(3) regulations will need to pass through Parliament under the affirmative procedure, unless the person making them declares that the regulation is not:

> "imposing or enabling the imposition of restrictions or requirements on or in relation to persons, things or premises in the event of, or in response to, a threat to public health" New section 45C(3)(c)

New section 45F further describes the scope of regulations that can be made by ministers under new section 45C and includes limiting the sanctions that can be applied to any new offences.

New section 45E prevents any regulation being made which requires a person to undergo medical treatment. Here, medical treatment includes preventative (prophylactic) treatment such as vaccination. The new section reinforces the situation under current law in the UK. Non-consensual treatment can only be forced on a patient if that patient lacks capacity to make decisions about his or her own treatment. Even then the treatment must be in that patient's individual best interests.

c. 45G - the role of a Justice of the Peace (JP)

This provision marks a fairly major change from the current situation, where local authorities have most of the powers relating to public health. New section 45M(1) describes the role of local authorities in the making of Part 2A orders (as the JP's orders

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[48] Revision of the International Health Regulations, 58th World Health Assembly

will be known). It is the responsibility of local authorities to apply for the orders. Others (new section 45(M)(4)) may apply for it to be changed or repealed. The role of the JP was one of the more controversial areas discussed in the response to the consultation[49]:

> As a general rule, a justice of the peace, rather than a local authority, should take the decision to require action of an individual person or in relation to individual premises or things.
>
> Twenty-two respondents answered yes to this proposal, and thirteen answered no. Those who answered no generally argued that the powers should rest instead with the local authority, and sometimes quoted approaches taken in health and safety and food safety legislation in support of this. We have considered this point carefully, but, like the majority of respondents, we believe that it is desirable to involve a JP to provide independent oversight, particularly as orders may deal, not only with commercial premises or business activities, but with individuals' private lives and homes. We are therefore taking this proposal forward.

New section 45G(1) describes some criteria that must be fulfilled for a JP to act, and 45G(2) what a JP can require a person (P):

> (a) to submit to medical examination;
> (b) to be removed to a hospital or other suitable establishment;
> (c) to be detained in a hospital or other suitable establishment;
> (d) to be kept in isolation or quarantine;
> (e) to be disinfected or decontaminated;
> (f) to wear protective clothing;
> (g) to provide information or answer questions about P's health or other circumstances;
> (h) to have their health monitored and the results reported;
> (i) to attend training or advice sessions on how to reduce the risk of infecting or contaminating others;
> (j) to be subject to restrictions on where P goes or with whom P has contact;
> (k) to abstain from working or trading

The Local Government Association expressed concern about the transfer of some of these powers from local authorities:[50]

> LGA View
>
> · The proposed changes to public health legislation are mainly sensible and will consolidate existing legislation into a framework that will meet new and emerging challenges
>
> · We believe the passing of powers from local authorities to JPs will create an additional layer of bureaucracy that will cause delays in response to incidents of

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[49] Review of Parts II, V and VI of the Public Health (Control of Disease) Act 1984: report on consultation, 15 November 2007

[50] Personal communication Local Government Association November 2007

> contamination. It will also cause confusion for businesses as powers under other legislation relating to hygiene and safety will remain with councils
>
> · The additional bureaucracy, as well as extension of powers to chemical and radiological contamination, will create new financial burdens for councils seeking to protect the public from infection and contamination.

New section 45G makes provision for a single (lay) JP to make a series of orders in respect of infected or contaminated persons who may present a threat to public health. The relevant orders include provisions that the persons submit to medical examination; be removed to a hospital or other suitable establishment; be detained in a hospital or other suitable establishment; be kept in isolation or quarantine; be disinfected or decontaminated.

It is not yet apparent what evidence would be required for a JP to make such an order, since new section 45G(7) indicates that this would be left for future regulations:

> "The appropriate Minister must by regulations make provision about the evidence that must be available to a justice of the peace before the justice can be satisfied as mentioned in subsection (1) or (3)."

45M provides for a procedure to vary or revoke orders. Officials have also indicated that the appeals mechanism provided for in section 67 of the *Public Health (Control of Disease) Act 1984* would apply (it is amended by paragraph 22 of Schedule 11). It may be worth noting that as currently drafted, that section provides for appeals from magistrates courts. New section 45G relates to a lay JP sitting alone.

Liberty, the human rights group, expressed concerns about the role of JPs in their consultation response:

> We welcome the concern shown in the consultation paper for due process and accountability indicated by the commitment in Proposal 6 that, as a general rule, justices of the peace rather than local authorities themselves should take the decision to require action of a person or action in relation to a particular thing.
>
> However, we consider that considerations of due process and accountability would be best served if decisions were taken not by justices of the peace acting alone, but acting together – i.e. as magistrates in the magistrates' court. In this way, the machinery of the court is available to record and solemnise the decisions taken[51].

New sections 45L(3) says detentions, isolations and quarantines must be time limited, up to a maximum of 28 days.

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[51] Liberty's response to the Department of Health Consultation: Review of Parts II, V and VI of the Public Health (Control of Disease) Act 1984

3. Disease Notification

Under the *Public Health (Control of Diseases) Act 1984* cholera, plague, relapsing fever, smallpox and typhus are notifiable to the local authority. The *Public Health (Infectious Disease) Regulations 1988* added a further list of diseases[52], and doctors are asked by local or national health authorities to notify on certain other diseases as well, without legislation.

The prime purpose of the notifications system is speed in detecting possible outbreaks and epidemics.

New section 45C(3)(a) would allow regulations to be made that brought all notifiable diseases under a single regulation. This would tidy up the current "two tier" legislation in the area. The regulations would also compel laboratories to report specific pathogens they find in samples in the laboratory. Currently, only doctors are required to notify of diseases they diagnose or suspect in patients.

It is expected that there will be a consultation on which diseases to include in the new regulations in autumn 2008.

Sections 45G(2)(g) and 45G(3) and (4) allow a JP to order people to reveal information about their own or other peoples health and circumstances, in order to allow efficient contact tracing. Contact tracing is a vital epidemiological tool for controlling outbreaks of transmissible disease, and an area where the public benefit may interfere with medical confidentiality.

4. Comments from other interested parties

The Association of Port Health Authorities[53] is "broadly in favour of the provisions of the new legislation"[54].

The British Medical Association said

> The BMA welcomes public health measures to help prevent and control the spread of serious diseases caused by infection and contamination and is supportive of measures to ensure that these powers are proportionate and do not involve compulsory treatment.[55]

This legislation leaves many specific points to regulations which are yet to be made. Beyond a general acknowledgement that reform of the law in the area was a "good thing", several interested parties expressed concern that powers made in regulation would be areas that they may wish to comment on further.

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52 *Public Health (Infectious Disease) Regulations 1988*
53 http://www.porthealth.co.uk/
54 personal communication November 2007
55 personal communication November 2007

V Health in Pregnancy Grant

Part 4 (clauses 121-128)

In his speech on the December 2006 *Pre-Budget Report*, Gordon Brown, then Chancellor of the Exchequer, announced that following "powerful representations" regarding the importance of good nutrition during the final stages of pregnancy, from April 2009 Child Benefit would be extended to all expectant mothers from week 29 of their pregnancy.[56] In September 2007 the Secretary of State for Health announced that the additional support would instead be in the form of a one-off payment, to be known as the Health in Pregnancy Grant.[57]

Part 4 of the Bill makes provision for the new payment, which is to be administered by HM Revenue and Customs. The Health in Pregnancy Grant – to be worth approximately £190 – will be non-contributory, non-income related and non-taxable. It will be available to all expectant mothers ordinarily resident in the United Kingdom, on condition of receiving maternal health advice from a health professional from 25 weeks of pregnancy. It will sit within the existing system of support for pregnant women, which includes the Sure Start Maternity Grant, and Healthy Start vouchers to help with the costs of milk, fruit and vegetables.

A. Existing support for pregnant women and young mothers

Financial support for pregnant women may have one of two objectives:[58]

- To provide a measure of income maintenance for women who, temporarily or permanently, give up paid work because they are expecting a child; or

- The need to protect the health of the mother and child by alleviating financial hardship.

Statutory Maternity Pay and the Maternity Allowance fulfil an income maintenance role. As far as meeting maternity expenses is concerned, provision was made within the post war National Insurance scheme for a maternity grant to help with certain immediate costs associated with birth. This later became a non-contributory benefit available to all mothers, but help was focused on low income families in 1987 with the introduction of the Social Fund. The Social Fund maternity payment was originally set at £85, approximately equal to the sum of the former contributory maternity grant and the average single payment for maternity needs made under the old Supplementary Benefit system.[59] It was increased to £100 in 1990 and remained at this level until it was replaced by the Sure Start Maternity Grant from June 2000.

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56 HC Deb 6 December 2006 c308

57 Speech by Alan Johnson given at Toynbee Hall, 12 September 2007: http://www.dh.gov.uk/en/News/Speeches/DH_078397

58 Wikeley, Ogus and Barendt, *The Law of Social Security,* 5th edition, 2002, p556

59 Wikeley, Ogus and Barendt, p488

1. Sure Start Maternity Grant

The Sure Start Maternity Grant was announced by the Chancellor in the March 1999 Budget:

> Today, we are announcing a new sure start maternity grant: Government offering more help to parents, but in return for parents meeting their responsibilities. Help amounting to £200 will be conditional, linked to keeping appointments for child health advice and child health check-ups.[60]

The payment was increased to £300 in December 2000 and to £500 in June 2002. Capital limits were abolished in October 2001.

The Sure Start Maternity Grant is available to recipients, or partners of recipients, of Income Support, income-based Jobseeker's Allowance, Pension Credit, Child Tax Credit (at a rate higher than the family element), or Working Tax Credit (which includes a disability or severe disability element). This is to ensure that the grant "is as widely available as possible amongst people with lower incomes".[61]

A claim must be made within the period beginning 11 weeks before the expected week of confinement and ending three months after the actual date of confinement. Entitlement is also dependent on the claimant having received advice on the health and welfare of the new baby (and on maternal health, where the application is made before the birth of a child) from a health professional (i.e. a doctor, midwife, health visitor or practice nurse). A certificate is included in the back of the benefit claim form which must be signed by a health professional confirming that advice has been given and the date of the consultation. "Health and welfare advice" is not defined in the regulations.[62] The current version of the Department for Work and Pensions *Guide for registered medical practitioners* in relation to medical certification for benefits purposes states:

> The precise nature of the advice provided is a matter for you but such advice will certainly be encompassed by current best clinical practice in maternal and child health care. [63]

In 2006-07 237,000 Sure Start Maternity Grants were made in Great Britain totaling £120 million[64]; in Northern Ireland, 8,800 awards were made at a total cost of £4.4 million.[65]

2. Healthy Start

The Healthy Start scheme replaced the Welfare Food Scheme across Great Britain from 27 November 2006. An identical scheme was introduced in Northern Ireland on the

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60 HC Deb 9 March 1999 c184

61 *Annual Report by the Secretary of State for Work and Pensions on the Social Fund 2006/2007*, Cm 7161, p5

62 *Social Fund Maternity and Funeral Expenses (General) Regulations 2005, SI 2005/3061*

63 IB204 August 2004, p34

64 Cm 7161, p17

65 Department for Social Development, *Annual Report on the Social Fund 2006/2007*, 19 November 2007

same date. The following Department of Health press notice issued to accompany the nationwide rollout gives details:[66]

> Families from low income households will benefit from a new scheme from Monday 27th November, giving free milk and fresh fruit and vegetables to children and mums-to-be.
>
> Healthy Start is replacing the Welfare Food Scheme, first brought in during the Second World War to help combat food shortages. Like the Welfare Food Scheme, Healthy Start will provide people who qualify with vouchers to buy milk and infant formula. However, the new scheme will provide greater flexibility, also allowing parents to buy fresh fruit and vegetables. Free vitamin supplements will remain an important part of the new scheme.
>
> The new vouchers will be worth £2.80 each. Qualifying pregnant women and children over one and under four will get one voucher every week, and children under one year old will get two vouchers a week. Vouchers can be spent with participating retailers - including small businesses and milkmen as well as larger supermarkets and chemists.
>
> Around 20,000 individual retailers across the UK have already signed up to participate in Healthy Start, more than had signed up to the Welfare Food Scheme. Retailers include food co-operatives, box schemes, markets, greengrocers and milk roundsmen as well as supermarkets and chemists.
>
> Public Health Minister Caroline Flint said:
>
> "Poor diet can have a real impact on people's health. We want people to have the best possible opportunity to eat healthily. But for families in low income households, this is sometimes easier said than done. This new scheme will not only provide greater choice of healthy food, but will also mean that children can get milk and fresh fruit and vegetables from the cradle up, helping to give them the best possible start in life."
>
> Over half a million low income households currently benefit from the Welfare Food Scheme. Eligible families will automatically move over to Healthy Start, but for the first time the scheme will also be open to all pregnant women under the age of 18 - a group known to be nutritionally vulnerable and at risk of having babies with a low birth weight. Pregnant women and children under four in families receiving certain benefits will also be eligible to receive the vouchers.
>
> Health professionals working with pregnant women and families with young children will have an important role in the scheme, providing them with advice and information on healthy eating and breastfeeding and supporting their applications for Healthy Start.
>
> Pregnant women and families on the new scheme will also be able to use the Healthy Start website to check if they qualify, download an application form, and find local shops participating in the scheme. The website also offers recipe ideas,

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[66] Department of Health press notice 2006/0365, *Healthy start rolls out nationwide*, 25 November 2006

tips for eating healthily during pregnancy and even recipe suggestions for weaning.

NOTES TO EDITORS

1. Healthy Start is open to pregnant women (once they are ten weeks pregnant) and children under four years old in families on the following benefits:

- Income Support
- income-based Jobseeker's Allowance
- Child Tax Credit (without Working Tax Credit) with an annual family income of below £14,155 (2006/7 figure).

It is also open to all pregnant women under 18 years of age even if they are not getting any benefits or tax credits.

2. Vouchers are worth £2.80. Pregnant women and children aged over one and under four will receive one voucher per week for each child/pregnancy. Children under one year old will receive two vouchers per child, worth a total of £5.60. If a baby is born early, they will receive the two vouchers until one year from their expected date of delivery ensuring they get extra help for longer. The value of the vouchers will be adjusted periodically to ensure they continue to keep pace with the retail prices of milk, fruit and vegetables and infant formula.

3. Evaluation of the scheme in Devon and Cornwall, where it has been running since 28 November 2005, showed that the scheme had been successfully implemented. Many families surveyed welcomed the new flexibility that Healthy Start vouchers offer and retailers found the process of registration and claiming payment to be simple and straightforward. Health professionals understood how the scheme worked and were able to advise their clients appropriately.

4. Retailers are currently being recruited to take part in the new scheme . Retailers who sell any of the Healthy Start foods can apply to register as a Healthy Start food outlet. Information and application forms for retailers are available from the Healthy Start Reimbursement Unit on [08707 201668] or at http://www.hsru.co.uk

5. Healthy Start is the culmination of several years of work to reform the Welfare Food Scheme. It builds on recommendations for change made by the Committee on the Medical Aspects of Food And Nutrition Policy (COMA) - following a review carried out in 1999, as well as feedback received during 2 public consultation exercises and extensive discussions with representatives of the health professions, retailers, and organisations working with disadvantaged women and families. The initial policy consultation was carried out in autumn 2002, and a second consultation on draft regulations to introduce the scheme into Devon and Cornwall in spring 2005.

6. More information about the new scheme, as well as recipes and healthy eating tips, is available on the Healthy Start website http://www.healthystart.nhs.uk

3. Child Benefit and the Child Tax Credit

Child Benefit is a universal benefit for all families with dependent children. It is paid to the “main carer” and since April 2007 has been worth £18.10 a week for the eldest

eligible child and £12.10 for each subsequent child. It is non-taxable and non-means tested.

The Child Tax Credit was introduced in April 2003 and consists of both a "family element" and an individual element in respect of each child (which is higher for disabled and severely disabled children). The amount received depends on family income; the individual elements are withdrawn first, so many families receive only the family element. The standard rate of the family element in 2007-08 is £545[67], but for families with a child under one year old an additional "baby element" of £545 is payable. For such families, therefore, the family element is worth a maximum of £1,090 a year. The "baby addition" to the family element is intended to recognise the costs on the family of responsibility for a baby.[68]

Neither Child Benefit nor Child Tax Credit can be paid in respect of any particular child for any period prior to their birth. Claims for Child Tax Credit are cross-matched with Child Benefit records, and people making a claim for Child Benefit are required to supply a birth certificate.[69]

In recent months there has been some controversy regarding payment of Child Benefit and Child Tax Credit to migrant workers in the United Kingdom for dependent children living in other EU member states.[70] This right to benefit stems from long-standing provisions in EU law on the co-ordination of social security systems within the European Economic Area (EEA)[71] which allow migrant workers from EEA countries to receive certain benefits from their host country for dependants living in their home country. The UK "family benefits" which may be paid for children living in another EEA country are Child Benefit, Child Tax Credit, and Guardian's Allowance. People claiming these benefits/tax credits must meet all the usual conditions for entitlement, but the ordinary residence and presence requirements for the child or children do not apply, provided the claimant comes within the scope of the relevant provision in EU law, namely Council Regulation (EEC) No. 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community.

A written answer on 17 September 2007 stated that at the end of June 2007 around 14,000 "A8" nationals[72] were receiving Child Benefit for a child or children living in another EEA country.[73]

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67 This starts to be withdrawn at incomes above £50,000 a year

68 HC Deb 19 April 2004 c373w

69 HC Deb 10 January 2006 c525w

70 See for example "Angela and her children live in Poland. So why are they and thousands more pocketing £1m a month in child benefits paid by British taxpayers?", *Daily Mail*, 22 September 2007

71 The EEA comprises the EU Member States plus Iceland, Liechtenstein and Norway. Switzerland is not a member of the EEA but as a result of an agreement with the EU that came into force on 1 June 2002, Swiss nationals enjoy broadly the same rights as EEA nationals with regard to freedom of movement.

72 The A8 countries are the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia

73 HC Deb 10 September 2007 c1968w

B. 2006 Pre-Budget Report announcement and subsequent statements

The 2006 *Pre-Budget Report* announced that, from April 2009, Child Benefit would be extended to every mother-to-be from week 29 of their pregnancy, in recognition of "the importance of a healthy diet in the final weeks of pregnancy and the additional costs faced by parents when their children are born".[74]

In its subsequent inquiry into the *Pre-Budget Report*, the Treasury Committee considered the Chancellor's reasons for extending support via Child Benefit rather than via (income-related) tax credits:[75]

> 69. We asked the Chancellor of the Exchequer why he had chosen to deliver additional financial support to expectant mothers by means of child benefit, which is available to all families regardless of their income, rather than by means of tax credits. He considered that it was the universal nature of child benefit that made it the most appropriate means of delivering additional support. He accepted that child benefit did not target those on low incomes, but emphasised the importance of assisting
>
> > all mothers at this particular point in their lives … not simply the poorest mothers … There are issues about nutrition and about the health of the mother as well as issues about the health of the child … I felt in these circumstances it is right to help all mothers and not just some mothers … I believe in child benefit.[274]
>
> He said that assistance for low-income families was the "second aspect" of the Government's policy, coming "on top of child benefit", in the form of the child tax credit.[275] The Chancellor of the Exchequer described the child tax credit as the "biggest single factor in reducing child poverty in this country in recent years, and the reason we met our first target and the reason we have reduced child poverty continuously".[276] Finally, he suggested that the Government was already "doing quite a lot" to help expectant mothers:
>
> > Support available for low-income families after 29 weeks includes a [Sure Start] maternity grant at £500 … There is a second element of our help as well, and that is support for diet and nutrition, where we provide between £6 and £12 a week for mothers for the nutrition of the mother-to-be and, then for the nutrition of the child in the years from 0 to 1. So for low-income families, in addition to child tax credit at a higher level, there is also available the maternity grant and, as I have just said, help in particular payments for nutritious food, including milk and other baby foods. So I think we are doing quite a lot to help mothers at this stage in their pregnancy and at the point at which a child is born … [277]

In a speech on 12 September 2007 the Secretary of State for Health set out the Government's case for further support for pregnant women in greater detail, but

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74 Cm 6984 December 2006, para 5.11

75 Treasury Committee, *The 2006 Pre-Budget Report*, 25 January 2007, HC 115 2006-07

announced that the additional help would be in the form of a one-off payment, to be known as the Health in Pregnancy Grant, rather than via Child Benefit:

> Improving public health is pivotal to our assault upon health inequalities, because lifestyle differences – such as smoking, diet and exercise – are responsible for as much as half of the gap.
>
> Many of the factors determining our health are established before we are even born.
>
> The World Health Organisation describes birth weight as the single most important determinant of a new born baby's survival; and there is a vast body of research to demonstrate how a baby's weight at birth determines their health in the future.
>
> In the short term, lower birth weight can lead to increased risk of cerebral palsy, visual impairment and deafness. In the medium term, it can slow down cognitive and physical development. In the long term, it can lead to chronic diseases such as diabetes and cardio vascular disease.
>
> If our mantra in the 1940s was "from the cradle to the grave", then our vision for the 21st Century should perhaps be "from the womb to the tomb".
>
> 8% of UK babies are classified as underweight, which is less than 5.5 pounds, compared to 6.4% across Europe. Many of these babies are born in deprived communities, where the mother's poor life choices can adversely affect the child's life chances.
>
> Mothers from deprived groups are over four times more likely to smoke during their pregnancy.
>
> We need more intensive support to help pregnant mothers: not just waiting for vulnerable mothers to come to us; but with nurses and midwives going into communities to spread the message.
>
> This approach has been pioneered in the US, with great success, and we are now developing a similar scheme aimed at disadvantaged mothers in ten deprived areas across the country.
>
> Of course, it is not just about support: it is also about cash, which represents a very real constraint on what expectant mothers can and can not do.
>
> Research by the Nutrition Policy Panel found that the average diets of pregnant women do not meet the recommended nutritional balance, but that it is the most disadvantaged women in particular who have the lowest nutritional intake.
>
> Even though it is an essential item, food is often one of the first areas where families will look for savings: it is one of the few outgoings, unlike rent, fuel, bills and council tax, where a struggling family can actually exercise some genuine choice and control.
>
> By April 2009, we will introduce a new Health in Pregnancy Grant, making a payment to each expectant mother. This will be in addition to Healthy Start vouchers, worth £2.80 a week.

> This substantial payment will be directly linked to improving nutrition – so it will be paid alongside nutritional advice, and the sum of money will be sufficient to help every mother eat healthily during her pregnancy.
>
> Of course, we won't send around the broccoli police if someone spends part of their grant on other items they may need in pregnancy. But, by supplementing valuable practical advice with necessary financial assistance, we are more likely to encourage expectant mothers to make responsible choices in a way that gives the child the best start in life. [76]

An HM Revenue and Customs press notice issued on the publication of the *Health and Social Care Bill* stated that Treasury Ministers had decided that the additional support would be in the form of a new one-off payment rather than an extension of Child Benefit, but gave no further explanation for the decision.[77]

C. Part 4 of the Bill

1. Overview

Part 4 of the Bill makes provision for a new one-off payment to expectant mothers ordinarily resident in the UK. The Department of Health website states that the payment – to be set initially at £190 – is intended to provide additional financial support to women in the last months of pregnancy "towards the costs of a healthy lifestyle, including diet, and with other additional costs faced at this time". The Health in Pregnancy Grant will "sit within the existing financial support system, providing support for women who may not receive any other support before the birth of their child".[78] The Department's website states:

> Entitlement to the Health in Pregnancy Grant will be linked to the requirement for pregnant women to seek health advice from a health professional. It may therefore provide a greater incentive for expectant mothers to seek the recommended health advice at the appropriate time.
>
> Women will be able to submit claims for the Health in Pregnancy Grant from the 25th week of pregnancy. This coincides with the guideline recommended 25th week antenatal appointment for women having their first pregnancy and 28th week appointment for subsequent pregnancies. This ensures that the burden on health professionals is kept to a minimum and arrangements for the Health in Pregnancy Grant are aligned with already established antenatal care. [79]

Further details of the proposed advice arrangements were set out in an HM Revenue and Customs press notice on 14 November:

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76 Speech by Alan Johnson given at Toynbee Hall, 12 September 2007: http://www.dh.gov.uk/en/News/Speeches/DH_078397

77 HMRC press notice NAT 74/07, *£190 grant to expectant mums – corrected copy*, 14 November 2007

78 *Health and Social Care Bill: Health in Pregnancy Grant*, 16 November 2007: http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSocialCareBill/DH_080449

79 ibid

> 3. The exact number of antenatal appointments and how often they occur will depend on a women's individual situation. Women expecting their first child are likely to have around 10 antenatal appointments and women have their second child around seven appointments.
>
> 4. The National Institute for Clinical Excellence (NICE) has set out the schedule and content of antenatal appointments. Women expecting their first child are likely to attend appointments before their 12th week, at 16, 18-20, 25, 28, 31, 34, 36, 38 and 40 weeks. Women expecting their second child are likely to attend appointments before their 12th week, at 16, 18-20, 28, 34, 36 and 38 weeks.
>
> 5. During early antenatal appointments women will be given information and advice about their maternity care and the choices available to them, maternity benefits, diet, other lifestyle advice such as smoking cessation, exercise and alcohol, and routine screening tests. The dietary advice includes information about the importance of nutrition, folic acid, and the consequences of excess levels of vitamin A, food supplements and food hygiene. Women receive health advice from their midwife and maternity healthcare professionals throughout their pregnancy, along with opportunities to discuss and ask questions, supported by antenatal classes and written information.[80]

While the health advice will be provided by health professionals, the grant itself is to be administered by HM Revenue and Customs.

2. Clauses 121-127: the new payment

Clause 121 is concerned with entitlement to the new payment in Great Britain. It inserts a new Part 8A (comprising new sections 140A and 140B) into the *Social Security Contributions and Benefits Act 1992* to provide that a pregnant woman who satisfies conditions to be prescribed in regulations is to be entitled to a lump sum to be known as the "Health in Pregnancy Grant". New section 140A(2) states explicitly that a condition may be that a woman has reached a specific stage of pregnancy. New subsection (3) states that a woman is not entitled to a payment unless she has received advice relating to "matters relating to maternal health" from a health professional. "Health professional" is to be defined in regulations. New subsection (3)(b) requires that the claimant is in Great Britain when she makes a claim, but new subsection (4) states that regulations may prescribe circumstances in which a woman is to be *treated* as being, or not being, in Great Britain for these purposes. Similar provisions currently exist for other benefits, allowing, for example, people accompanying a child receiving medical treatment abroad to be treated as if they are in Great Britain for benefit purposes.

New section 140B states that the amount of the grant is to be specified in regulations. The Government has already indicated that the payment will be £190, but new section 140B(2) allows the Treasury to prescribe "different amounts …in relation to different cases".

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[80] HMRC press notice NAT 74/07, *£190 grant to expectant mums – corrected copy*, 14 November 2007

Clause 122 makes provision for the administration of the Health in Pregnancy Grant by amending the *Social Security Administration Act 1992* and the *Social Security Act 1998*. Subsections (1) and (2) allow the Commissioners of HM Revenue and Customs to make regulations regarding claims for the new grant. This could, for example, cover the manner in which claims must be made, time limits, and the provision of information to enable entitlement to be determined.[81]

Subsection (3) provides that claimants will have to satisfy the "National Insurance number (NINo) requirement" that currently applies to claims for most social security benefits and tax credits. This was introduced by the *Social Security Administration (Fraud) Act 1997*.[82] It stipulates that a benefit claimant, and anybody on whose behalf a claim is being made, must either have a NINo or provide the evidence to enable them to be allocated one.[83]

Subsections (4) and (5) provide that the rules governing recovery of overpayments of the Health in Pregnancy Grant will be the same as those which currently determine whether an overpayment of a social security benefit can be recovered. In order for an overpayment to be recoverable under social security law, it must have been caused by a "misrepresentation, or failure to disclose, a material fact" by the claimant (whether fraudulent or otherwise).[84]

Decisions and appeals mechanisms will also mirror those for social security benefits (subsection (7)).

Subsection (6) enables information held by HMRC in relation to the Health in Pregnancy Grant to be used to determine whether a claimant is also entitled to the Sure Start Maternity Grant (see above).

Clause 123 amends the *Social Security Administration Act 1992* to enable HMRC to impose a civil penalty on a person who fraudulently or negligently makes an incorrect statement or declaration, or who gives incorrect information or evidence, in relation to a claim for a Health in Pregnancy Grant. The clause also provides for a right of appeal to an appeal tribunal against a decision to impose a penalty. A penalty may not exceed the amount of the grant.

Clauses 121-123 apply to Great Britain only. **Clauses 124-126** make equivalent provision for Northern Ireland. **Clause 127** provides that the Health in Pregnancy Grant is an excepted matter in Northern Ireland, and is therefore outside the competence of the Northern Ireland Assembly.

Clause 128 provides for HMRC to be responsible for the payment and management of the grant.

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81 *Health and Social Care Bill Explanatory Notes*, Bill 9-EN, para 440

82 See Library Research Paper 96/107, *The Social Security Administration (Fraud) Bill*

83 For further information see Stewart Wright, "NINO knowledge", *Welfare Rights Bulletin* 198, June 2007: http://www.cpag.org.uk/cro/wrb/wrb198/NINO.htm

84 section 71 *Social Security Administration Act 1992*

Subsection (2) amends section 115 of the *Immigration and Asylum Act 1999* to provide that a person subject to immigration control is excluded from entitlement to the Health in Pregnancy Grant. A "person subject to immigration control" is defined in section 115(9) of the 1999 Act as a person who is not a national of an EEA state and who:

- requires leave to enter or remain in the United Kingdom but does not have it; or
- has leave to enter or remain which is subject to a condition that they do not have recourse to public funds; or
- has leave to enter or remain given as a result of a formal undertaking by another person to maintain them.

This is the main provision which excludes people coming to the UK from overseas from entitlement to benefits.

Subsection (4) exempts the Health in Pregnancy Grant from liability to income tax.

The *Explanatory Notes* state that the Health in Pregnancy Grant is to be funded from the Consolidated Fund. Expenditure on payments in the first year (2009/10) is estimated at £175 million; this is based on Office for National Statistics projections of 780,000 births a year. Expenditure in subsequent years is expected to be lower (£145 million a year in 2010/11 and 2011/12); the figure is higher for the first year of the new benefit as there will be more claims in that year, from women in their final weeks of pregnancy at April 2009 who satisfy the conditions for entitlement on the date of introduction.[85]

Implementation and running costs are estimated as follows:

2007/08	£1.1 million
2008/09	£8.4 million
2009/10	£5.3 million
2010/11	£4.8 million

The higher figure for 2008/09 reflects initial development costs of the new IT system.[86]

D. Comments and responses

In his original announcement at the time of the 2006 *Pre-Budget Report*, the then Chancellor mentioned that he had received "powerful representations" about the need to better recognise the extra costs faced by pregnant women in the last months of pregnancy and in the first weeks after birth, but gave no further details of the sources.[87]

Responses to the Government's plans for giving additional financial support to pregnant women have been mixed. An HMRC press notice on 14 November 2007 included favourable comments from both the Royal College of Midwives and the Royal College of Nursing:

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85 Bill 9-EN, para 546
86 Bill 9-EN, para 545
87 HC Deb 6 December 2006 c308

> Welcoming the new measure, Louise Silverton, Deputy General Secretary of the Royal College of Midwives, said:
>
> "The Royal College of Midwives is pleased that the financial costs of pregnancy for women and their families has been recognised. This will help women to make essential purchases before the baby's arrival. Crucially it will also encourage pregnant women to live a healthier life, which is vital for them and the long term development of their babies. This is the very start of life and we are building the foundations for a baby to become a healthier adult. I would encourage women to speak to their midwife so that they can make the best use of the grant and make the right health choices for themselves and their baby."
>
> Dr Peter Carter, General Secretary, Royal College of Nursing, said:
>
> "The RCN has been working closely with Government in developing the Health in Pregnancy Grant and we look forward to seeing further detail of the proposals. The RCN is supportive of the underlying principle of the Government's plans to take active steps to send out a positive message to women about the importance of keeping good health during pregnancy. To ensure this is effective we would be particularly supportive of any policy measures to ensure that expectant mothers have improved access to advice on living a healthy lifestyle from healthcare professionals. It is also important for the grant to be non-means tested and available to all pregnant women, as their continued health during pregnancy is important for themselves, their baby and their family."[88]

In response to the speech given by the Secretary of State for Health on 12 September 2007 in which he announced the Health in Pregnancy Grant, the National Childbirth Trust welcomed the recognition that pregnancy was an expensive time, but argued for a wider strategy to improve nutrition focusing on the earlier stages of pregnancy:

> The National Childbirth Trust (NCT) charity welcomes the recognition that pregnancy and the birth of a new baby is an expensive time. In order to make a difference to women' diets during pregnancy, and to the health of babies, this grant should be part of a wider, co-coordinated strategy to improve awareness on the importance of nutrition around the time of conception and during early pregnancy - when it would be more likely to have an impact. For instance, individual information on the value of taking folic acid and vitamin D supplements early in pregnancy would also help outcomes for mothers and babies. In addition, increasing the value of Healthy Start vouchers - a Government initiative - (currently valued at £2.80 a week for milk, vegetables and fruit) would be a way to reach disadvantaged women at an earlier stage in their pregnancy.[89]

An article in the *Observer* on 9 September on the proposals expected to be announced that week included the following quote from Tam Fry, director of the Child Growth Foundation:

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88 HMRC press notice NAT 74/07, *£190 grant to expectant mums – corrected copy*, 14 November 2007

89 Quote by Rosemary Dodds, Policy Researcher at the National Childbirth Trust, in National Childbirth Trust press notice, *Health in Pregnancy Grant*, 12 September 2007: http://www.nct.org.uk/media/pressrelease?prid=100

> We know that women who are well educated and with disposable income take their diet seriously during pregnancy and eat well, but for those lower on the social scale, without the education or the money or the help, it's tough. It's a sensitive issue to address, but it matters because the weight of a baby at birth can have a profound effect on their health further down the line.
>
> By the time a woman falls pregnant, she already needs to be eating well to give her baby the best chance. Tackling it halfway through the pregnancy is really a bit late, though it is very good that the government is waking up to the scale of the problem.[90]

An article in the *Daily Telegraph* on 10 September included the following quotes from Daghni Rajasingam, a consultant obstetrician and spokesman for the Royal College of Obstetricians and Gynaecologists:

> "If a woman is not already eating a healthy diet by that stage, then encouraging them to eat more fruit and vegetables from 29 weeks is too little too late.
>
> "Even for small babies it is too late, there is very little you can do to increase growth at that stage.
>
> "It is gimmicky," Dr Rajasingam added. She said pre-pregnancy education about diet would be more effective.[91]

Both the Conservatives and the Liberal Democrats have criticised the proposed new grant. The *Independent* on 16 November reported:

> The Conservatives criticised the efficacy of the scheme. "It is vital to improve public health but it can't be done with one-off gimmicks," said Andrew Lansley, the shadow Health Secretary. "This proposal does not appear to result from evaluation of any pilot scheme."
>
> He added: "This Labour Government has presided over growing health inequalities. For the Government now to be talking about enhanced interventions with mothers in deprived areas is deeply hypocritical when the number of midwives hasn't kept pace with the increase in births over the last five years."
>
> Community midwife teams should give mothers more advice, screening and support, he said.
>
> The Liberal Democrats described the grant, first outlined by Gordon Brown in his pre-Budget report in 2006, as "an abject waste" of taxpayers' money. "It smacks of a typical New Labour gimmick that tries to address a serious social issue by throwing money at it," said its health spokesman Norman Lamb.
>
> "The proposal serves to highlight the shameful health inequalities that have embarrassingly widened under this Government. There needs to be far more

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90 "Pregnant women to get cash for good diet", *The Observer*, 9 September 2007
91 "Pregnant women to get £120 for fruit and veg", *Daily Telegraph*, 10 September 2007

> done to get across the value of healthy diets, especially during pregnancy, but this sort of state handout will likely achieve nothing of any substance."[92]

The independent think tank The King's Fund is also critical of the proposal. Its Chief Executive, Niall Dickson, commented:

> This is a silly proposal. The case for one-off payments to new mothers to get them to improve their diets is far from convincing, to say the least. Financial incentives can be effective but work best when payments are regular and sustained and when addressing simple health behaviours. Quite how a limited cash payment seven months into a pregnancy will have any impact on the health of the child or the mother is hard to see.[93]

VI Miscellaneous Provisions

Part 5 (clauses 129-148)

Unless otherwise stated, information on these provisions is drawn from the Bill's Explanatory Notes, its Impact Statement and the pages of the Department of Health's website devoted to the Bill.

1. Duty of Primary Care Trusts

All NHS bodies are currently under a duty under section 45 of the *Health and Social Care (Community Health and Standards) Act 2003* to ensure they have arrangements in place for the purpose of monitoring and improving the quality of care. Clause 129 would amend the NHS Act 2006 to insert a duty on Primary Care Trusts to make arrangements to secure continuous improvement in the quality of care provided by or for them. This new version of the duty is intended to be more closely aligned with the duty imposed on English local authorities by section 3 of the *Local Government Act 1999*. The existing duty in section 45 of the 2003 Act would cease to apply in relation to English NHS bodies. Responsibility for the duty of care would thus be placed with the commissioners of NHS services, the Primary Care Trusts.

2. Transfer of the global sum for pharmaceutical services

There are two different sources of finance that pharmacies receive for providing community-based NHS pharmaceutical services (e.g. dispensing fees) in England. One of these is the funding held centrally by the Department of Health, known as the "Global Sum". The other source of finance, which funds the cost of drugs and medicines, is currently included in the sums allocated to Primary Care Trusts (PCTs) annually to meet their general expenditure. There are similar provisions in Wales where Local Health Boards carry out functions similar to those of PCTs.

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92 "Pregnant women to be offered £120 'good food' grants", *Independent*, 16 November 2007

93 King's Fund press notice, *King's Fund responds to the Queen's Speech*, 6 November 2007

The Bill would make changes to the *NHS Act 2006* to move the funding of pharmaceutical services now funded by the Global Sum to PCTs, and make changes to the *NHS (Wales) Act 2006* to make similar arrangements in relation to Local Health Boards.

A consultation documents issued in July 2007, *Modernising financial allocation arrangements for NHS pharmaceutical services 2007,* [REF] explains the background. The Department of Health says that devolving central funding for pharmacy contractors is a natural progression and in keeping with moves to devolve NHS funds to the frontline.

3. Extension of the NHS indemnity scheme in England to include non NHS providers of NHS care

The Clinical Negligence Scheme for NHS Trusts (CNST) indemnifies members against losses and liabilities arising out of negligence occurring in NHS care. It is currently only available to specific NHS bodies (under section 71 of the *NHS Act 2006*). When the schemes were first established most NHS care was provided directly by NHS bodies but in recent years, non-NHS bodies have started to deliver NHS care and the Secretary of State also procures some NHS services directly.

Clause 131 would enable the regulations that established the CNST to be amended so that the Secretary of State and non-NHS bodies treating NHS patients could benefit from the same cover that is available to NHS bodies

4. Weighing and measuring of children

Under the National Child Measurement Programme (NCMP) children in maintained schools in England in the reception year (aged 4 to 5 years) and in Year 6 (aged 10 to 11 years) are weighed and their heights measured. School nurses from the Primary Care Trust (PCT) oversee the weighing and measurements. Schools are asked to provide the PCT staff undertaking the NCMP with a list of children to be weighed and measured, and to inform the PCT if parents have chosen to opt out of the programme. Information about individual children's weights or heights is not automatically given to parents though they may request their child's information. The records of children's heights and weights are anonymised and the data are used within the NHS for the analysis of trends in obesity, and overweight and underweight children.

The NCMP is one aspect of the Government's programme to tackle obesity. The current arrangements are described on the Department of Health website[94] and there is a Department for Health leaflet for parents, *Why your child's weight matters,* published by the NHS.[95] There is guidance for PCTs on arrangements for measuring the height and weight of children currently covered by NCMP. The guidance sets out the legal basis for the current programme; the responsibilities of PCTs; the role of schools and local

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94 http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Healthyliving/DH_073787 last updated on 16 November 2007

95 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073655

authorities; the schools covered; and, lists the data collected and how they are stored and used.[96] There is separate guidance for schools.[97] This explains how schools can support the programme: by informing parents, providing class lists to the PCT, identifying a suitable location for the measurements to be taken, and explaining the programme to pupils. Parents should receive a letter explaining the purpose of the programme which provides them with the opportunity to withdraw their child from it if they wish. The guidance notes that the Government's legal advice is that consent from parents/carers is not needed for children to be weighed and measured for the NCMP (for the detailed reasons, see paragraph 6 of the guidance). There is also a Question and Answer guide for teachers.[98]

Earlier in the year, the Department of Health commissioned research on parental attitudes towards the NCMP. The Department of Health noted that among its main conclusions were that:

- parents generally valued feedback of the height and weight data as well as information on whether the child is a healthy weight or not
- the report found that attitudes towards the exercise were generally positive. However, advance information, the choice to opt-out and the provision of feedback were deemed important elements of a measurement programme
- parents generally felt that provision of the height and weight with an information leaflet about healthy lifestyles would be informative and helpful and such information could be put into practice by parents[99]

The Bill seeks to improve the effectiveness of the National Child Measurement Programme. It enables the Secretary of State to make regulations to provide that all parents whose children participate in the programme receive the results routinely, unless they have opted out of the programme. The Bill also allows for the programme to be extended to early years settings and to other primary school year groups. The Explanatory Notes on the Bill explain that the regulations made under the Bill will enable the aggregated data gathered to be used for performance management purposes, for example, as part of the new Local Government National Indicator Set, which will inform negotiation of Local Area Agreements.[100]

Commenting on the Bill's provisions, the Department of Health website states[101]:

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96 *The National Child Measurement Programme: guidance for PCTs - 2007–08 school year*, Department of Health, September 2007: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078689

97 *Guidance for schools 2007-8*, http://www.teachernet.gov.uk/docbank/index.cfm?id=11918

98 http://www.teachernet.gov.uk/_doc/11928/Pupils_QA_07-08_-_final[1].pdf

99 *Research into parental attitudes towards the routine measurement of children's height and weight*, Department of Health, November 2007: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080600

100 Health and Social Care Bill, Explanatory Notes, paragraph 52

101 http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Healthyliving/DH_080606

What information will be fed back?

Under the new provisions, we envisage that PCTs will feedback each child's height and weight to parents, whether or not the child's weight is a matter for concern. The data will be accompanied by information to help parents interpret whether their child is a healthy weight or not, tips on healthy living and signposting to follow-up services as necessary.

We will be working with parents, professional groups and organisations to develop the best system and format to provide the information, and ensure it is handled in a sensitive manner.

Further information for Health Professionals
Detailed processes have not yet been finalised and we will be discussing arrangements with key stakeholders. We will provide further detail about providing the results to parents as part of the NCMP, in the coming months.

This policy change does not apply to the 2007-08 programme. PCTs should continue to provide the results back to parents who have requested them, and not provide them on a routine basis.

We will provide PCTs with further guidance on the process for feeding back to parents, including template letters and advice on the level/format of information for parents. We will be hosting regional workshops to discuss routine feedback, and other aspects of the NCMP.

Further information for Parents

These results are not 'warning letters'. All parents will receive the results for their child following the measurement, unless they decide not to receive the information.

The NCMP is an important programme in our efforts to tackle childhood obesity. Without accurate data local areas can not plan and commission the children's health services they need. We therefore encourage parents to let their child participate, and not withdraw them, even if parents are not interested in receiving their child's results.
We are looking to commission research on what information, in what format, parents would like to receive. There is also an online child height weight calculator, which will help parents interpret their child's results at:
www.direct.gov.uk/childweight (opens new window)

Wales

At present the NCMP does not extend to children in Wales though many NHS trusts record height and weight at school entry, and some record it at Year 6, but this is not undertaken on a consistent basis, and the data are not recorded and analysed centrally.

The Bill will allow Welsh Ministers to make provision by regulation for the weighing and measuring of pupils under 12 in Wales.[102]

Obesity in junior school age children: the figures

At present the Department of Health advise that the most authoritative source of data on childhood obesity[103] is the Health Survey for England (HSE)[104].

The table below reproduces data from the HSE[105] and shows that the number of children age 2 to 10 years who are overweight or obese is on the increase. In 2005, 31 per cent of children aged 2 to 10 years in England were either overweight or obese compared with 22.7 per cent in 1995. The proportion of children who were overweight increased from 12.8 per cent in 1995 to 14.2 per cent in 2005, while the proportion of obese children rose from 9.9 per cent to 16.8 per cent over the same period.

In 2005, the prevalence of obesity for boys and girls aged 2 to 10 is similar. Obesity rose from 9.6 percent in 1995 to 16.9 percent in 2005 for boys, while for girls obesity rose from 10.3 percent to 16.8 percent over the same period. Slightly fewer girls than boys were overweight in 2005: 12.2 per cent and 16.1 per cent respectively.

Overweight and obesity prevalence among children aged 2-10 years by gender, England 1995 to 2005

									unweighted data[1]			weighted data[1]		
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2003	2004	2005
Boys														
Overweight	12.9	13.8	13.1	14.6	14.1	13.6	15.6	13.3	14.7	14.2	16.5	14.6	14.6	16.1
Obese	9.6	11.0	11.1	11.4	16.1	12.2	13.5	15.2	14.9	16.2	16.6	15.1	15.9	16.9
Overweight including obese	22.5	24.8	24.3	26.0	30.2	25.8	29.1	28.5	29.6	30.4	33.1	29.7	30.5	33.0
Girls														
Overweight	12.6	11.0	12.0	12.5	13.5	11.6	14.0	13.1	13.4	14.2	12.2	13.4	14.8	12.2
Obese	10.3	10.2	10.7	11.8	13.0	11.8	12.7	15.8	12.5	11.9	16.7	12.4	12.8	16.8
Overweight including obese	22.9	21.2	22.6	24.3	26.5	23.3	26.7	28.9	25.9	26.1	28.9	25.8	27.7	29.0
All children														
Overweight	12.8	12.4	12.5	13.6	13.8	12.6	14.8	13.2	14.0	14.2	14.3	14.0	14.7	14.2
Obese	9.9	10.6	10.9	11.6	14.6	12.0	13.1	15.5	13.7	14.3	16.7	13.8	14.5	16.8
Overweight including obese	22.7	23.1	23.4	25.2	28.4	24.6	27.9	28.7	27.7	28.5	30.9	27.8	29.1	31.0
Bases (weighted)														
Boys	*1261*	*1418*	*2007*	*1336*	*633*	*570*	*1035*	*2364*	*876*	*416*	*695*	*878*	*379*	*664*
Girls	*1266*	*1365*	*2082*	*1216*	*628*	*523*	*1094*	*2290*	*897*	*343*	*724*	*858*	*346*	*674*
All	*2527*	*2783*	*4089*	*2552*	*1262*	*1094*	*2129*	*4654*	*1774*	*759*	*1419*	*1736*	*726*	*1338*

1. From 2003 data were also weighted for non response. Data weighted for child selection only are provided for consistency with previous years.
Source:
Health Survey for England 2005 - updating of trend tables to include 2005 data. The Information Centre

While current estimates of childhood obesity rely on survey data, it is anticipated that more comprehensive and complete data will be available within a few years. The Government has already launched the National Child Measurement Programme (NCMP)

[102] Health and Social Care Bill, Explanatory Notes, paragraphs 53 and 54 and 473 to 475
[103] The main measure of obesity is the Body Mass Index (BMI), defined as weight (kg) divided by the square of height (m^2): a BMI of 25 to 30 is defined as overweight and over 30 is classed as obese.
[104] *Analysis of the National Childhood Obesity Database 2005/06.* Department of Health: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsStatistics/DH_063565
[105] http://www.ic.nhs.uk/webfiles/publications/opan06/obesity%2C physical activity and diet tables.xls

to collect height and weight measurements in schools for Reception (4-5 years old) and Year 6 (10-11 years old) classes. Data was first collected in 2005-06 but is not yet seen as reliable due to teething problems with the introduction of the scheme and anecdotal evidence that heavier children were more likely to opt out of the measurement process.

As noted earlier, clauses in the *Health and Social Care Bill* aim to improve the effectiveness of the NCMP by enabling aggregated and anonymous data to be used for performance management purposes as part of the new Local Government National Indicator Set. The legislative changes also make provision for all parents of children who take part in the NCMP to receive their child's results, regardless of their weight, unless they request otherwise. The Government believes that giving the results to parents is a vital way of engaging both children and families with issues about healthy lifestyles and weight.

5. Direct Payments in lieu of the provision on care services

Direct payments were first introduced in 1997 for working age adults[106]. They are local council payments for people who have been assessed as needing help from social services, and who would like to arrange and pay for their own care and support services instead of receiving them directly from the local council. The aim of direct payments is to increase individuals' independence and choice by giving them control over the way the services they receive are delivered. They were extended to older people in 2000, and in 2001 to parents of disabled children and carers. In 2003, Regulations made under the *Health and Social Act 2001* put a duty on councils to make direct payments to individuals who consent to and are able to manage them, with or without assistance.[107]

Under current legislation, in order to qualify for direct payments, an individual must be able to consent to receiving the payments. So people who lack capacity,[108] and are therefore unable to give this consent, cannot receive direct payments.

In its 2006 White Paper, *Our Health, our care, our say*,[109] the Government stated its intention to extend direct payments to those groups who are excluded under the current legislation. The Bill helps to deliver this commitment by amending section 57 of the *Health and Social Care Act 2001* to include a regulation making power in respect of those who lack capacity. Clause 134 would allow regulations to provide that a designated suitable person mayreceive direct payments on behalf of another person who has been assessed as needing community care services but lacks capacity to consent to the making of those payments.

A new subsection 1C to section 57 of the *Health and Care Act 2001* defines a "suitable person" in relation to a person who lacks capacity (P):

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[106] *Community Care (Direct Payments) Act 1996* (repealed)
[107] *Community Care, Services for Carers and Children's Services (Direct Payments) (England) Regulations 2003* (SI 2003/762)
[108] As defined by section 2 of the *Mental Capacity Act 2005*
[109] Department of Health. January 2006. Cm 6737.

- as a representative of P;
- as a person who is not a representative of P, but who is considered by P's surrogate and by the responsible local authority as a suitable person to receive direct payments for P; or
- in cases where there is not a representative or surrogate of P, a person who the responsible local authority considers to be a suitable person for the purposes of receiving direct payments for P.

The term "representative" will be defined in Regulations.[110] The term "surrogate" is defined as a deputy appointed by the Court of Protection under the *Mental Capacity Act 2005* or a donee of a lasting power of attorney created by P.

6. Abolition of the liable relative rule

Under the *National Assistance Act 1948,* where services are provided to a person at public expense under that Act, the person's spouse is liable to maintain them. This means that a local authority may ask a liable spouse to refund all or part of the public expenditure, subject to their own income and expenditure.[111] This provision is often referred to as the "liable relative rule". Unmarried couples are not legally liable to maintain one another even though they may live together as husband and wife.

In 2003, the Department of Health stated that it was planning to repeal the liable relative rule at the earliest opportunity.[112] The Department of Health's latest version of the *Charging for Residential Accommodation Guide*[113] (CRAG) strongly encourages local authorities not to apply the rule pending its repeal. It states:

> These provisions are now widely regarded as anachronistic, and the Government has announced its intention to repeal them. In the consultation on changes to the CRAG in October 2003 and April 2004 the Department notified local authorities that it planned to take steps to have the rule repealed at the earliest opportunity. The removal of the rule will require a change to primary legislation and the Department is seeking an appropriate legislative vehicle at the earliest possible opportunity. The hope is that the liable relatives rule will be repealed not later than April 2007. **In the interim, the Department would strongly encourage local authorities to exercise their discretion to NOT apply the liable relatives rule.**[114]

Clause 135 would abolish the liable relative rule by amending the *National Assistance Act 1948.* The clause also makes consequential amendments to other provisions affected by the repeal.

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[110] New section 57(5A) of the *Health and Social Care Act 2001*
[111] Section 43
[112] Department of Health, *Proposed Changes to Residential Care Charges from 12 April 2004: Consultation*, 15 December 2003, p2. http://www.dh.gov.uk/assetRoot/04/06/72/03/04067203
[113] Department of Health, April 2007. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073650
[114] *Ibid,* para 11.002

7. Ordinary residence

Section 24 of the *National Assistance Act 1948* sets out how a person's ordinary residence is determined for the purposes of deciding which authority will be responsible for the provision of their residential accommodation. Currently, a person will continue to be ordinarily resident in the area in which he was ordinarily resident immediately before he was admitted to hospital. Clause 136 would extend the ordinary residence rule to cover accommodation provided other than by an NHS hospital. Clause 136 also amends the 1948 Act to provide that the Secretary of State and the Welsh Ministers may make arrangements for determining how cases involving ordinary resident disputes should be determined. An equivalent provision to determine ordinary resident disputes would be inserted into the *Chronically Sick and Disabled Act 1970* and would apply where a local authority provides welfare services under section 2 of that Act.

8. Financial Assistance for social enterprises

The White Paper *Our Health, Our Care Our Say,* published in January 2006[115] included a commitment to support and encourage social enterprises in health and social care. The Bill's EN say that there is no single definition of a social enterprise and there are many legal form but a general description would be "businesses with primarily social objectives whose surpluses are principally reinvested for that purpose in the business or in the community". In August 2007 a Social Enterprise Investment Fund (SEIF) was established but existing powers to make grants, loans and guarantees are limited.

Clauses 137-144 would provide for the Secretary of State to have the power to finance social enterprises delivering health and social care, subject to certain qualifying conditions. (This is intended to include, for example, a social enterprise providing support services to NHS providers.) The Secretary of State would also be able to finance any person wanting to set up a social enterprise to deliver such services. The Secretary of State would be able to delegate these powers to NHS Trusts, Primary Care Trusts, Strategic health Authorities, Special Health Authorities, and other organisations such as companies.

The clauses extend to England and Wales but apply only in relation to social enterprises providing services in England.

9. National Information Board for Health and Social Care

Clause 145 would establish a National Information Board for Health and Social Care to be known as the National Information Governance Board, which among other things, would have responsibility for the NHS Care Record Guarantee for England. (This sets out the rules that will govern information in the NHS Care Records Service, which is

115 http://www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Modernisation/Ourhealthourcareoursay/index.htm

being implemented as part of the National Programme for IT in the NHS and which has already caused concerns in relation to patient confidentiality etc.)

The EN say that a review of information governance carried out in 2005 by Harry Cayton, then National Director for Patients and the Public at the Department of Health, identified nine different bodies or groups developing, contributing to or interpreting information governance, with no single co-ordinating body. Since then most of the bodies identified have been closed, merged or do not have a national role in information governance, and an interim Governance Board has been put in place. However, there still remains one of the bodies identified, the statutory Patient Information Advisory Group, which the Bill would replace with the new Governance Board. Local responsibility for information governance would not be affected by these measures.

10. Functions of the Health Protection Agency in relation to biological substances

Clause 147 would abolish the existing National Biological Standards Board (NBSB), which was established under the Biological Standards Act 1975 and transfer its functions to the Health Protection Agency (in line with the aim of the Department of Health's Arm's Length Body Review to reduce the number of arm's length bodies). The clause would also give enable the Health Protection Agency to be given any other functions that could have been given to the NBSB.

In a statement on the Department of Health website, the Government outlines its intentions in relation to the abolition of the National Biological Standards Board[116]

> The abolition of the National Biological Standards Board and the transfer of its functions to the Health Protection Agency, 16 November 2007
>
> The Health Protection Agency (HPA) is one of the Department of Health's Arm's Length Bodies. It is a global first as a one-stop shop dedicated to protecting the health of the public from infections, chemicals, poisons and radiation.
>
> The National Biological Standards Board (NBSB) is another of the Department's Arm's Length Bodies. It has a role in the standardisation and testing of biological substances which it performs through its executive arm, the National Institute for Biological Standards and Control (NIBSC). NIBSC is a science-based organisation whose task is to assure the quality of biological medicines for human use.
>
> The Department of Health's Arm's Length Body (ALB) Review, announced in 2004, aims to rationalise and reduce the number of ALBs and generate efficiency savings, including through sharing of core functions.
>
> One of the outcomes of this review was that the NBSB should be abolished and its functions transferred to the HPA. Certain NIBSC functions and activities complement those of the HPA and the two bodies already work together in a

[116] Department of Health website, as at 20 November 2007

number of important areas such as pandemic influenza planning and vaccine evaluation. This merger will strengthen and enhance this work further, as well as increasing overall efficiency.

This clause in the Health and Social Care Bill will therefore effect the abolition of the NBSB (by repeal of the Biological Standards Act 1975) and transfer its functions, currently discharged through NIBSC, to the Health Protection Agency.

This merger will not change how the NIBSC operates. Its international and national role will be maintained following the merger.

After the arm's length review the proposed merger was consulted on with stakeholders.[117]

54. The consultation has been a valuable source of stakeholder views and it is encouraging that the responses have delivered sensible, coherent suggestions to the questions and issues. Additionally, the wide range of bodies represented by the responses indicates a fair assessment of the issues by those who are directly affected.

55. It is therefore agreed that:

- The NIBSC will be transferred in its entirety to the HPA;
- The NIBSC 'brand' will be retained post-merger, whilst acknowledging the NIBSC's new position operating as within the overall framework of the HPA;
- The HPA will be subject to a direction of the Secretary of State to set up a committee of the HPA Board with delegated Board authority to act as the independent authority to deal with the NIBSC *regulatory* issues where there is a conflict of interest within the HPA;
- A final governance model will be employed to reflect this 'NIBSC' committee while incorporating the remainder of the NIBSC's functions in the current identified HPA structure

56. In addition to this, in the process of merging the two bodies, the HPA will need to consider:

- Effecting the decisions detailed above
- Linking the objectives of NIBSC to the other parts of HPA and other health entities as appropriate;
- Ensuring retention of the NIBSC 'brand' post-merger;
- Maintaining the identity/purpose and future funding (subject to wider financial constraints) of the NIBSC;
- That while the HPA needs to be free to determine its own operating structure, it should take account of the issues raised at question 9 (paragraph 49 – above).

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[117] Consultation document for NIBSC stakeholders - Department of Health formal responses, 15 May 2006

Another option for the NIBSC was that it should merge with the Medicines and Healthcare products Regulatory Authority (MHPRA). The consultation report noted this.[118]

> However, one respondent (the University of Surrey) did decline to reply to the questionnaire as they considered the NIBSC should be transferred in its entirety to the MHRA, and considered that answering the individual questions would indicate tacit support for the proposal to transfer to the HPA
>
> ***Do you think any of NIBSC's current functions should be discontinued, or transferred to an organisation other than the HPA?***
>
> 'While it is possible to envisage that regulatory functions such as batch release could be transferred to the MHRA, we believe that such a transfer would be detrimental because those functions should be carried out by personnel who have the scientific background and laboratory capabilities not only to assess the data but to pursue and resolve technical issues as they arise.'
> International Association of Biologicals
>
> 28. If the current functions of the NIBSC remain in one entity, the only alternative suggestion to the HPA as a new 'home' was the MHRA. This option was considered as part of the ALB review and discounted as it had no support. In addition, as the MHRA is an Executive Agency of DH, transferring the NIBSC staff into the Civil Service would cut across the whole ethos of both the ALB review, and the desire to move appropriate work out of the Civil Service.

The HPA was established as a special health authority (SpHA) in 2003. On 1 April 2005, the National Radiological Protection Board (NRPB) was incorporated into the HPA and the agency established as a non-departmental public body. Incorporation of the NRPB as well as the NBSB integrates the work of these bodies enabling a single body to coordinate an "all hazards" approach to pubic health issues, as espoused in the WHO IHR (2005).

The NBSB described how it has been working towards integration with the HPA for some time.[119]

> NIBSC's merger with HPA was delayed due to lack of time for legislative changes in the current Parliamentary year but we have continued to build close relationships throughout the two organisations.
>
> Our Finance team and functions have been integrated with those of HPA and the new, Oracle-based, financial accounting system has been successfully implemented. In addition there has been excellent co-operation in many areas, notably Information Technology, and Human Resources, where shared experience has been beneficial to both organisations.

At a strategic level, the NIBSC Director now attends the HPA Executive Group on a regular basis, cross representation at Board level was increased, and a framework for

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[118] Consultation document for NIBSC stakeholders - Department of Health formal responses , 15 May 2006
[119] NBSB Annual Report & Accounts 2006/07

NIBSC's governance within the HPA has been proposed, taking account of our specialist regulatory functions.

Appendix

This appendix contains briefings on the Health and Social Care Bill which the Library has received. They represent only a sample of organisations that might have views on the subject. They are listed in alphabetical order.

Association of British Dispensing Opticians, the Association of Optometrists and the Federation of Ophthalmic & Dispensing Opticians

Health and Social Care Bill

Response from the Association of British Dispensing Opticians, the Association of Optometrists and the Federation of Ophthalmic & Dispensing Opticians.

Together the Association of British Dispensing Opticians, the Association of Optometrists, the College of Optometrists and the Federation of Ophthalmic & Dispensing Opticians represent the 10,000 optometrists, 5,000 dispensing opticians and optical businesses who provide high quality and accessible eye care services in the UK.

We endorse the principles that regulation of healthcare professionals should be proportionate, accountable, consistent, transparent and targeted. Optometrists and dispensing opticians do not carry out invasive or life-threatening procedures and there is a high level of skill and training for both optometrists and dispensing opticians. Moreover there are very high levels of service quality and patient satisfaction and a very low level of complaints in the optical sector. We believe that regulation of the sector should be proportionate to this low level of risk.

Against that background we welcome the publication of the Health and Social Care Bill and the creation of the new office of the Office of the Health Professions Adjudicator which builds on the separation of functions already established by the General Optical Council.

Like many others, we do have concerns about the lowering of the standard of proof in fitness to practice cases but are willing to work with the General Optical Council and Office of the Health Professions Adjudicator to get the new system right for both patients and the professions.

We also support the shift of emphasis to a system that seeks to support good practice including retraining and education rather than punishing bad practice in the few cases in optics where this is necessary.

For further information please contact Heather Marshall by email; heathermarshall@aop.org.uk or by phone 020 7202 8157

British Dental Association

British Dental Association

Briefing on

The Health and Social Care Bill

November 2007

Care Quality Commission – regulation of health care

Regulation of dental practice

1. The British Dental Association supports the regulation of private dental practice by the Care Quality Commission. We are also pleased that our concerns that private and NHS practice should be subject to the same requirements have been heard. This reflects the fact that the majority of dental practices undertake both private and NHS care and this provision should avoid duplication and overlap of regulatory and inspection regimes.

2. It is, however, not clear on the face of the Bill, nor from the Impact Assessment, how primary care will fit in, although we have been advised that dentistry will be included at an early stage. We seek clarification of how the functions of PCTs in relation to NHS practice will be taken over by the Commission. There should be no duplication of inspection and no confusion between registration requirements and those relating to NHS contracts. It will be important to avoid overlap and to ensure that it is clear to dentists holding NHS contracts to whom they are responsible for which obligations. There will also need to be no detriment safeguards at first registration with the Commission in relation to acquired rights to carry on a dental business.

3. The Bill provides for registration and regulation to be proportionate to the risks involved. We support this intention and stress the importance of cost-effectiveness both for the regulator and regulated, particularly where regulated organisations are small, independent units. Regulation should also be developmental and a positive experience for organisations. It should not take disproportionate time away from patient care, give rise to significantly increased costs for little obvious benefit, nor impose requirements that appear to be unrelated to the needs of the sector.

Standards

4. There is to be another new set of standards, determined by the Secretary of State. A great deal of work has been done to apply the current *Standards for Better Health* to dental practice and we question the need for yet another set so soon since they were updated in 2006.

Timely consultation and involvement

5. Early professional engagement with the development of the new arrangements is essential and we look forward to consultation on the regulations and other provisions as they are drafted. Frequently dentistry is involved too late and has to fit into systems that are designed for other healthcare settings. We repeat the need to tailor the requirements to the different sectors, in our case to dental practice. Another important aspect is that any reports on healthcare providers should take account of the special circumstances of small, personal units.

The commissioning role of Primary Care Trusts

6. We are pleased to see the Commission's role in ensuring the quality and efficiency of healthcare providers and of Primary Care Trusts' commissioning arrangements. PCTs need help, support and training to enable them to fulfil their commissioning function to a high standard, particularly in commissioning dental services where we have found very variable performance and understanding.

Regulation of health professionals

7. Our main concerns in the proposals for regulating health professionals in the future relate to the adoption of the civil standard of proof, for which no real arguments have been put forward, and, more generally, the need not to undermine the confidence of regulated professionals in their regulators.

Membership of regulatory bodies

8. Members of the professions are seriously concerned about the loss of a professional majority in the membership of regulatory bodies. Not only does this undermine their confidence in the regulatory function, but it deprives the Councils of professional expertise in highly technical occupations. This is particularly acute in the case of dentistry, where the General Dental Council regulates not only dentists but six types of dental care professionals. It is impossible to ensure appropriate input with such a small membership.

Standard of proof

9. We are deeply concerned by the move away from the criminal standard of proof, particularly in cases where the allegation is grave and the individual's registration (and therefore livelihood) is called into question. This is particularly worrying given that erasure from the Dentists Register is now to be for a minimum of five years. Taking away the right to practise for such a period requires it to be beyond

reasonable doubt that the circumstances are grave and are proven. In dentistry, five years effectively equate to a life ban and the end of their career.

10. In terms of proportionality, the standard of proof must be commensurate with the gravity of the allegation and the seriousness of the consequences. There might be arguments for a lower standard of proof to be applied where a less grave allegation is made and a lesser sanction is appropriate. But, without an assurance that there would be a sliding scale whereby consideration of the loss of the right to practise demanded that the adjudication panel were satisfied so as to be sure, we cannot support the change. We do not see that this is incompatible with the need to protect the public, given the range of sanctions available and the possibility of applying a sliding scale which culminates in the criminal standard in grave cases.

11. A further argument in favour of the criminal standard in these cases is the fact that evidence is admissible in fitness to practise hearings that would not normally be admissible in a court of law. This in itself is accepted, but it requires a balancing safeguard.

Council for Healthcare Regulatory Excellence

Referral of ill health cases to the High Court

12. The Bill proposes that, in addition to conduct and competence cases, the CHRE can refer to the High Court regulators' decisions relating to impairment of fitness to practise due to ill health. Currently, ill health cases are treated confidentially. How can confidentiality continue to be assured?

Membership

13. We are disappointed to see no provision for representation of the regulators in the constitution of CHRE. Inclusion would enhance CHRE's ability to carry out its functions and the professions' confidence in the Council's interpretation and application of regulatory excellence.

Sharing of information on healthcare professionals

14. We accept that the various responsible bodies need to be aware of significant information relating to a health professional, in order that the public is appropriately protected. It is essential, however, that there are adequate safeguards to ensure the accuracy, currency, security and relevance of the information. Regulations and guidance must make very clear what sort of information is permissible, how it is to be shared and with whom.

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British Medical Association

Parliamentary Brief

Regulation of the Medical Profession - Health and Social Care Bill
Second reading, House of Commons, 26 November 2007
(This document applies to the UK)

The prime objective of any regulatory system for the medical profession should be to protect patients and to support doctors with performance difficulties. The vast majority of doctors perform well and safely, and acknowledge that it is imperative that patients are protected from the small number of cases of unsafe doctors. The BMA therefore fully supports measures that promote excellence in medical practice and that help to reduce instances of poor standards, negligence or criminality among doctors. We also support regular checks for doctors – revalidation - provided they are fair and workable.

The public has repeatedly demonstrated its trust in doctors[120] and this public trust must be maintained. Part of that trust lies in the fact that good doctors will act as their patients' champions, if necessary fighting for the right drug, the best treatment, and the patients' freedom to choose where they receive it.

The Government announced its intention to change the way doctors are regulated in the UK in a white paper, Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century (February 2007). Part 2 of the Health and Social Care Bill includes provision to amend the legislation governing doctors.

The BMA's position on the Government's proposals
Some improvements to the regulation of the medical profession are needed, but any reform must be workable in practice and maintain a system in which both the public and doctors can have confidence that fairness and justice will be delivered. The greatest protection for the public is to have a system where doctors feel able to admit to faults or failings in themselves and colleagues, confident in the knowledge that these will be dealt with in a fair, sensitive and supportive manner.

The BMA is concerned that some of the Government's proposals are not only unfair to doctors but will compromise their clinical independence with consequent risks to patient care. There is a strong sense among doctors that many of the proposals, when taken together, will amount to the loss of professionally-led regulation.

- The BMA strongly opposes Clause 104 which imposes a requirement for all the health professional regulatory bodies and the new Office of the Health Professions Adjudicator to use the civil standard of proof (the balance of

[120] Ipsos MORI poll commissioned by the Royal College of Physicians , 1 November 2006.

probabilities) in fitness to practise cases. The General Medical Council currently uses the criminal standard (beyond reasonable doubt). It would be an injustice to remove a doctor's livelihood based on a lower standard of proof than is used currently.

- The BMA also has concerns about the removal of the adjudication function from the General Medical Council (GMC) and therefore the creation of a separate body, the Office of the Health Professions Adjudicator. We are also very worried about the role of the proposed "responsible officers" because we see them as having a conflict of interest between their various roles.

The loss of professionally-led medical regulation has the potential to compromise doctors in their role of speaking out for their patients with consequent risks to patient care. With a state-owned NHS which is virtually a monopoly employer, doctors could be compromised in their ability to use their clinical independence to get the best treatment for their individual patients, diminishing their professionalism and with consequent risks to patient care. This could also lead to the practise of defensive medicine which is not in the best interests of either patients or the NHS budget.

Standard of proof – Clause 104

The government and the General Medical Council are dropping the criminal standard of proof in adjudicating fitness to practise cases based on concerns about a doctor and instead will adopt the civil standard of proof. Although it is proposed that the civil standard of proof will be applied flexibly, the BMA strongly opposes this change.

The criminal standard of proof of "beyond reasonable doubt" is very clear. The balance of probabilities, as applied in the civil standard of proof, is more complex.

It cannot be right that a doctor's means of earning a living will be determined on a balance of probabilities. There will be many discussions in the coming months about the proposal to operate a flexible civil standard of proof. If a doctor stands to lose his or her livelihood then the BMA remains convinced that nothing less than the criminal standard will do.

On 20 August 2007, the GMC launched a consultation on implementing the civil standard of proof in fitness to practise hearings.

- Although the GMC's proposed change is lawful, and the BMA has responded to the document, we are concerned that the GMC is consulting on ***how*** to implement the change before Parliament has debated and voted on ***whether*** to introduce this move.

We note that clause 104 cannot be amended without resorting to primary legislation [clause 104(4)(a)]. The BMA is concerned that if, as we fear, the adoption of the civil standard leads to miscarriages of justice for doctors, the standard cannot easily be changed back to the criminal standard.

Adjudication function and the creation of the Office of the Health Professions Adjudicator (OHPA)

Clause 91 proposes the establishment of the Office of the Health Professions Adjudicator (OHPA). Schedule 7 amends the Medical Act 1983 to transfer from the

GMC the functions relating to the adjudication of fitness to practise cases thereby separating the investigation of fitness to practise cases from their adjudication.

The BMA does not believe the case has been made for establishing a separate body and does not accept that the medical profession should lose the authority to regulate itself. Given that the GMC has already separated its adjudication function, making it independent of the investigation procedures, it is unclear what the evidence base is for creating a new body and how this will improve judgments on such cases. Although the Bill does include some detail about the operation of the OHPA, much still remains to be clarified and the BMA expects to be consulted on these in due course. We await information, in particular, on how the new body will be funded.

- The procedural rules, clauses 98 (3) and (4) make reference to the award and assessment of costs and expenses. The BMA understands that these subclauses relate only to those practitioners regulated by the General Optical Council, but we would welcome clarification of this on the face of the Bill.

- As part of its duty to inform the public, Clause 100(3)(a) indicates that the OHPA **may** withhold from publication "information concerning the physical or mental health of a person which the OHPA considers to be confidential". We would have deep concerns if confidential information about the health of a doctor were made publicly available and therefore suggest that the OHPA be prohibited from publishing such information and not be given discretion in the matter.

- The transition from the GMC's fitness to practise panels to those of the OHPA will require careful planning and management and the BMA calls for information on how this will be organised and a timescale for it.

Council for Healthcare Regulatory Excellence (CHRE)
Clause 105 renames the Council for the Regulation of Health Care Professionals. Clause 105(3) amends the CHRE's main objective so that it is "to promote the health, safety and well-being of patients and other members of the public." This seems to be very close to the GMC's purpose, set out on its website, which is "to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine". The two bodies are distinct and we would not wish to see the CHRE's objectives encroaching on those of the doctors' regulatory body.

Clause 109 gives the CHRE additional powers to refer to the High Court, or the Court of Session, cases relating to impairment of fitness to practise on grounds of ill health. Its current powers allow it to refer cases only relating to misconduct and professional competence. The BMA has concerns about this extension of the CHRE's powers as we do not believe that information about a doctor's health should be made public in this way. At present, the GMC's fitness to practise panels meet in private when considering confidential information about a doctor's health and we believe that the confidentiality of such information should be respected in any subsequent proceedings.

Currently, if the CHRE has reason to believe that a GMC fitness to practise panel has imposed too lenient a sanction on a doctor, it may refer the case to the High Court, or the Court of Session. Clause 109 changes this so that the CHRE loses its power in this regard. Instead, the GMC and General Optical Council are given powers (Schedule 7) to refer these cases to the High Court, or the Court of Session following adjudication by

OHPA. We are unclear about the timing of this as powers are being removed from the CHRE and given to the GMC and GOC in relation to decisions to be made by the OHPA when this body has not yet been established. The BMA is seeking clarification on the transitional arrangements.

Composition of the GMC Council

The BMA has long argued in favour of a medical majority on the GMC's Council to retain professionally-led regulation and the profession's confidence in the regulator. The White Paper proposed that the GMC should have, as a minimum, parity of membership between lay and medical members. The BMA does not support the government's view that the existence of a medical majority undermines the GMC's independence.

Currently, an Order in Council cannot impose a lay majority on the Council of a regulatory body. The BMA is very concerned to note that paragraph 4(3) of Schedule 8 (page 152) changes this and could pave the way for the imposition of a lay majority on the GMC. This causes the BMA great concern.

Responsible officers

Clause 110 inserts a new section 45A into the Medical Act 1983 to require designated bodies employing doctors to appoint or nominate "responsible officers". Designated bodies would include NHS trusts and primary care trusts in England. All practising doctors would be expected to relate formally to a "responsible officer" who would have responsibilities relating to the evaluation of fitness to practise of doctors.

The BMA has concerns that the existence of this role could seriously blur employment and regulation functions. We believe that there is potential for patronage and prejudice if too much authority is placed in the hands of single individuals. The notion of embedding regulatory power within an employing organisation is of concern as it is likely that the responsible officer will be working alongside the colleagues whom they will be regulating – a complex and undesirable organisational arrangement.

We believe strongly that the "responsible officer" function should be separate from the employment one, as regulation has to be independent of the employer if it is to retain professional confidence and credibility. The information in the Bill about the role of these individuals does nothing to assuage our concerns.

It is essential that the public trust in the medical professional is maintained and deserved. Ministers must address the BMA's concerns in order to achieve legislation that has the confidence of the public, employers and doctors.

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22 November 2007

Commission for Social Care Inspection

a. HEALTH AND SOCIAL CARE BILL

Briefing Note by the Commission for Social Care Inspection for Second Reading Debate
26 November 2007

VII Introduction

The Government intends to create a new social care and health regulator, the Care Quality Commission, bringing together the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Act Commission via the Health and Social Care Bill in this Parliamentary session. The bill was introduced in the Commons on 15 November 2007.

The bill is likely to complete its Parliamentary stages and receive Royal Assent by the summer of 2008.

The Government intend (subject to the passage of the legislation) that the Care Quality Commission will be established in October 2008 and will take on its full powers from April 2009. The Government also intends that full implementation of the new regulatory framework for health and social care providers will take place from April 2010.

The Health and Social Care Bill

The full purposes of the bill are to:

- Create a new integrated regulator for health and adult social care, the Care Quality Commission, bringing together some of the existing health and social care regulators into one regulatory body.
- Reform professional regulation to enhance public and professional confidence and strengthen clinical governance as part of the Government's response to the Shipman Inquiry.
- include provisions to make a one off payment to all expectant mothers from the 29th week of pregnancy.

The main elements of the bill are:

- To establish a new, integrated health and adult social care regulator, from existing regulators; to define the functions of the new regulator in the areas of safety and quality assurance, information and performance assessment and safeguarding the rights of detained mental health patients.
- To update the system of registration that applies to providers of health and adult social care services and extend this to include NHS providers.

- To introduce legislation to use the civil, rather than criminal, standard of proof for all healthcare professional regulatory bodies; to create an independent adjudicator to undertake independent and objective formal adjudication for the professional regulatory bodies.
- To ensure that all healthcare organisations employing or contracting with doctors appoint a 'responsible officer' with personal responsibility to work with the GMC to identify and handle cases of poor professional performance by doctors.

VIII The Care Quality Commission

The proposed new Commission will have a very broad remit. It will be responsible for assessing and inspecting the safety and quality of services which together:

- Account for some 30% - around £105bn – of discretionary public expenditure in 2007-08 plus significant private expenditure on healthcare and adult social care (where approximately one-third of people fund their own care)
- Employ some 2.9 million people, also across the public, private and voluntary sectors
- Are delivered through well over 30 000 individually registered care and health services, in the public, private and voluntary sectors. Some 24 000 of those are in the social care sector the vast majority of which are small or medium enterprises.

IX CSCI's Position

The Commission's public statements to date have been to regret the timing of the 'merger' because there has not been sufficient time to bed down the new regulatory system and given that this will be the third change in regulator since 2002.

However, CSCI does recognise that this will happen subject to Parliamentary approval. Accordingly CSCI wishes to ensure that social care continues to have a strong voice and that the new body has the best possible structure for social care. We support the Secretary of State in his view that social care should be placed at the heart of the new body. We therefore express our position on the bill in terms of risks to avoid and ways in which it can be improved upon to achieve this.

We welcome our work with the Department of Health on parts of the new structure and also welcome the fact that the Government has made some positive changes to its original proposals. For example, we are pleased to see that the new Commission will have the power to look at and comment upon both health and social care commissioning.

However, we have four themes which we hope Parliament will consider in its assessment of the bill.

1. The New Body Should Retain a Strong Social Care Focus

WHILE THERE ARE GOOD ARGUMENTS THAT HEALTH AND SOCIAL CARE SHOULD BECOME MORE CLOSELY INTEGRATED WE HAVE STRONG CONCERNS THAT SUCH A "MARRYING UP" IS DONE IN A WAY THAT AVOIDS HEALTH DOMINATING AND BECOMING THE MAIN FOCUS OF THE NEW BODY.

For example, there are concerns that additional duties for the Care Quality Commission unless they are separately and adequately funded (such as any stemming from the current focus on the cleanliness of hospitals), will cause already tight resources to move from the social care to the health side.

As Baroness Pitkeathley said in the debate in the Lords on the Queen's Speech:
"…the Commission for Social Care Inspection has been of the utmost importance in championing social care, highlighting successes and failings and providing a strategic lead for the whole sector. The Health and Social Care Bill announced in the gracious Speech will contain provisions to create what I understand will be called the Care Quality Commission—to replace the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. It will require all providers of health and social care to be registered and a consistent approach to regulation and inspection will no doubt bring benefits to patients and to service users. But we must ensure that the expertise built up by CSCI and shown to such advantage in reports such as The State of Social Care in England, published in January this year, is not lost.
In addition, CSCI has a fine record in making the views of users and carers not just known but central to its functioning. We must ensure that this continues with the new body. It will have a smaller budget, but this is one area where we must not cut corners. We must remain concerned that the institutional attention of the new body does not become entirely focused on healthcare at the expense of social care and that resources are balanced accordingly."
We also have concerns that having a unified approach to the registration of both social care and health bodies may cause difficulties in practice. For example, a large acute hospital is a very different type of concern to a small domiciliary care agency. Furthermore the vast majority of the 24 000 social care providers are small or medium sized enterprises in contrast to the large hospital based providers. We would like to ensure that duties in the bill can work equally effectively on the social care as well as the health side.

2. The New Body Should Build on Existing Progress

The Government has stated that it wants the new Commission to carry forward and improve upon the progress that CSCI has made in the last three years. For example, CSCI has always taken a regulatory approach that is fully committed to putting the views and experiences of those who use social care services, and their families and carers, at the centre of our work, as evidenced by such activities as our "Experts by Experience" programme.

As Baroness Howarth of Breckland said in the Lords debate on the Queen's Speech:

"We need a regulator who, apart from monitoring existing services…has the same commitment to users as the Commission for Social Care Inspection has demonstrated under the leadership of Dame Denise Platt. Progress since the commission's inception has been strong, with an increase in 2005-06—for the fourth consecutive year—in the average percentage of minimum standards met in the services inspected by the commission…As the Healthcare Commission merges into the new super-regulator, the Care Quality Commission, I would ask the House to ensure that, in its consideration of the Bill at all stages, the voice of social care is strongly maintained and carried forward. It would be wrong not to note that there are serious concerns in the social care and voluntary sectors about the proposed merger. Too many people are closely affected by these services."

WE BELIEVE THE BILL SHOULD ENSURE THAT NOT ONLY ALL CSCI'S CURRENT POWERS ARE TAKEN FORWARD, BUT ALSO THAT THE POSITIVE WORK THAT CSCI HAS CARRIED OUT OVER THE LAST THREE YEARS IS PROTECTED. WE WANT TO ENSURE THAT THE 2003 ACT IS BUILT UPON IN THE LIGHT OF CSCI'S EXPERIENCE. SIMPLY CARRYING OVER THE POWERS OUTLINED IN CSCI'S ENABLING ACT[121] MAY NOT BE ENOUGH TO DO SO, ESPECIALLY IF THE NEW BODY IS PERCEIVED TO BE DOMINATED BY HEALTH ISSUES.

IT MAY BE THAT THE BEST WAY OF DOING THIS IS TO ENSURE THAT THE STRUCTURE OF THE NEW COMMISSION IS SUCH THAT IT REPRESENTS PEOPLE WITH BOTH HEALTH AND SOCIAL CARE INTERESTS.

3. THE NEW BODY SHOULD TAKE A "RIGHTS BASED APPROACH"

CSCI BELIEVES, IN LINE WITH GENERAL GOVERNMENT POLICY, THAT THE NEW REGULATOR SHOULD TAKE A STRONG RIGHTS BASED APPROACH TOWARDS THE PEOPLE WHO USE HEALTH AND SOCIAL CARE SERVICES. THE NEW COMMISSION SHOULD PLACE THE RIGHTS OF THE PEOPLE WHO USE SERVICES AND THEIR CARERS AT THE HEART OF ITS WORK AND THEY SHOULD HAVE CLEAR RIGHTS OF ACCESS TO IT. WE WOULD WANT TO ENSURE THAT THIS APPROACH IS REFLECTED THROUGHOUT THE LEGISLATION.

4. THE NEW BODY SHOULD RETAIN INDEPENDENCE

THE BILL DELEGATES MANY MATTERS TO SECONDARY LEGISLATION. THE CURRENT ARRANGEMENTS WITH THE DEPARTMENT OF HEALTH WORK WELL. DH IS CSCI'S SPONSOR DEPARTMENT AND ARE ACCOUNTABLE TO PARLIAMENT FOR OUR WORK AS WELL AS AGREEING OUR ANNUAL BUDGET WITH US. HOWEVER, WE WANT TO ENSURE THAT THE NEW BODY STILL REMAINS AN INDEPENDENT REGULATOR RATHER THAN BECOME AN "ARMS LENGTH" BODY WITH MANY OF THE DECISIONS ABOUT HOW IT OPERATES BEING MADE DIRECTLY BY MINISTERS THROUGH REGULATION (WHICH WILL PERHAPS NOT RECEIVE THE SAME LEVEL OF PARLIAMENTARY SCRUTINY).

SPECIFIC ISSUES FOR CONSIDERATION

[121] Health and Social Care (Community Health and Standards) Act 2003

ON SOME PARTS OF THE BILL WE HAVE SOME MORE DETAILED POINTS TO MAKE.

INDEPENDENT REVIEWS AND STUDIES: WE WELCOME THE FACT THAT A CONTINUED POWER TO MAKE INDEPENDENT STUDIES, REVIEWS AND REPORTS (IN ADDITION TO THE ANNUAL "STATE OF SOCIAL CARE REPORT") WILL BE MAINTAINED WITHOUT THE NEED FOR DIRECT SECRETARY OF STATE APPROVAL.

WE BELIEVE THAT THE NEW REGULATOR SHOULD HAVE THIS POWER "COMMENCED" AT THE INCEPTION OF THE NEW BODY.

CSCI CONSIDERS THAT SUCH REPORTS ARE CRUCIAL IN PROVIDING AN EVIDENCE BASE FOR DRIVING UP SOCIAL CARE STANDARDS AND QUALITY ACROSS THE PIECE AND ARE CRUCIAL TO REPORTING ON THE STATE OF SOCIAL CARE. IT IS ARGUABLE THAT THE CHAIR AND BOARD OF THE NEW COMMISSION WOULD BE BEST PLACED TO DECIDE WHAT REPORTS THE NEW BODY SHOULD MAKE AND WHEN IT SHOULD MAKE THEM TAKING ACCOUNT OF DH VIEWS BUT NOT RELIANT ON DIRECT APPROVAL. TO DO OTHERWISE WOULD SEEM TO UNDERMINE THE INDEPENDENCE OF THE NEW REGULATOR. AND IT IS ONLY BY EXERCISING ITS INDEPENDENCE THAT SUCH A REGULATOR CAN BE OF SERVICE TO THE PUBLIC AND SUPPORT IMPROVEMENT IN THE SECTORS. INDEED, WITHIN ITS FIRST YEAR OF OPERATION CSCI CARRIED OUT THREE MAJOR REPORTS WHILE DEALING WITH ITS OWN ESTABLISHMENT AND REVIEWING THE WAY IT CARRIED OUT ITS NASCENT REGULATORY FUNCTIONS.

THE NEW CHAIR AND COMMISSION MEMBERS: THE CSCI SUBMISSION TO THE CONSULTATION ON THE *GOVERNANCE OF BRITAIN GREEN PAPER* MADE THE FOLLOWING POINTS:

"THE GREEN PAPER SUGGESTS A GREATER ROLE FOR SELECT COMMITTEES IN THE RECRUITMENT PROCESS FOR CERTAIN PUBLIC APPOINTMENTS. WE AGREE THAT GREATER SCRUTINY WILL INCREASE BOTH ACCOUNTABILITY AND TRANSPARENCY AND WELCOME THIS PROPOSAL. WE BELIEVE THAT THE POSTS OF CHAIR AND CHIEF EXECUTIVE/CHIEF INSPECTOR OF OFCARE [AS IT THEN WAS] SIT VERY WELL WITHIN THESE PROPOSED ARRANGEMENTS AND SHOULD BE SUBJECT TO SUCH PRE-APPOINTMENT PARLIAMENTARY SCRUTINY."

WHILE DECISIONS ON WHICH POSITIONS ACROSS THE PUBLIC SECTOR THIS NEW SCRUTINY WILL APPLY TO WILL BE MADE IN CONSULTATION WITH APPROPRIATE DEPARTMENTS - GIVEN THE SIZE AND IMPORTANCE (TO THE PEOPLE WHO USE SERVICES) OF THE NEW REGULATOR - WE BELIEVE THAT SELECT COMMITTEES SHOULD HAVE A ROLE IN THESE APPOINTMENTS.

WE BELIEVE THAT THE NEW BODY SHOULD BE FULLY REPRESENTATIVE OF SOCIAL CARE AS WELL AS HEALTH. WE ALSO THINK THAT THE NEW COMMISSION NEEDS TO PLACE THE PEOPLE WHO USE SERVICES, THEIR FAMILIES AND THEIR CARERS AT THE HEART OF WHAT IT DOES. WE ARE NOT CONVINCED THAT THE CURRENT PROPOSAL FOR AN ADVISORY COMMITTEE IN ITSELF ACHIEVES THIS.

GOVERNANCE ISSUES: OUR RESPONSE TO THE CONSULTATION ALSO MADE THE FOLLOWING POINTS ON THE GOVERNANCE OF THE NEW COMMISSION:

"THERE IS ALSO THE MORE SPECIFIC GOVERNANCE ISSUE THAT, IN OUR VIEW, THE CARE QUALITY COMMISSION SHOULD HAVE A NON-EXECUTIVE COMMISSION TO SET STRATEGIC DIRECTION AND HOLD THE SENIOR MANAGEMENT TO ACCOUNT.

THIS MODEL HAS WORKED VERY WELL FOR CSCI AND IT PROVIDES WELCOME CLARITY AS TO ROLES AND ACCOUNTABILITIES. WE DO NOT REGARD OTHER MODELS, SUCH AS UNITARY BOARDS WITH BOTH NON-EXECUTIVES AND EXECUTIVES AS FULL MEMBERS, AS PROVIDING THE SAME DEGREE OF CLARITY AND ACCOUNTABILITY.

THE NON-EXECUTIVE COMMISSION MODEL WOULD ALSO, IT SEEMS TO US, BE MORE IN LINE WITH THE 'INDEPENDENT REGULATORS' REPORT BY THE BETTER REGULATION TASK FORCE AND CURRENT CABINET OFFICE GUIDANCE ON NON-DEPARTMENTAL PUBLIC BODIES."

RESOURCING: THE GOVERNMENT IS ALREADY BEARING DOWN HARD OVER THE NEXT TWO YEARS ON THE RESOURCES AVAILABLE TO CSCI AND THE HEALTHCARE COMMISSION (WHETHER FROM GOVERNMENT GRANT OR PROVIDER FEES). THE GOVERNMENT HAS ALSO SAID THAT THE NEW BODY WILL HAVE TO OPERATE ON A SUBSTANTIALLY SMALLER BUDGET THAN THE COMBINED CURRENT BUDGETS OF CSCI, THE HEALTHCARE COMMISSION AND THE MENTAL HEALTH ACT COMMISSION.

BECAUSE OF THIS WE WOULD WANT TO ALSO ENSURE THAT WHENEVER A FRESH DUTY OR NEW FUNCTION IS GIVEN TO THE NEW BODY (FOR EXAMPLE AROUND THE NEW DUTIES AROUND HOSPITAL ACQUIRED INFECTIONS AND REGISTERING NHS BODIES) THAT THE GOVERNMENT PROVIDE RESOURCES TO MEET THE NEW BURDENS.

OTHER ISSUES: A LARGE NUMBER OF MORE DETAILED MATTERS WILL ALSO NOT BE ON THE FACE OF THE BILL BUT WILL BE GOVERNED BY SECONDARY LEGISLATION. FOR EXAMPLE, THE WORK ON A NEW SYSTEM OF REGISTRATION REQUIREMENTS WITH WHICH PROVIDERS MUST COMPLY STILL HAS A LONG WAY TO GO. A CONSULTATION IS PROMISED ON THIS, TO WHICH WE WILL CONTRIBUTE FULLY IN THE LIGHT OF OUR EXPERIENCE OF THE CURRENT REGULATORY REGIME. THE NEW BODY NEEDS TO BE FOCUSED ON OUTCOMES FOR PEOPLE THAT USE SERVICES AND REFLECT THE INTERESTS OF STAKEHOLDERS.

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Council for Healthcare Regulatory Excellence

Position statement number 1
General briefing from the Council for Healthcare Regulatory Excellence on the Health and Social Care Bill

Key messages

- We welcome the implementation of the White Paper *Trust, Assurance and Safety* in the Health and Social Care Bill
- We support proposals to make CHRE an authoritative independent voice for patients in the regulation of health professionals
- We are concerned that the Bill should contain all the necessary clauses to enable CHRE to carry out its new roles and responsibilities.

The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[122]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

Trust, Assurance and Safety and the Health and Social Care Bill

The Government proposes new arrangements for the regulation of health professionals in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in secondary legislation and in the Health and Social Care Bill, in this parliamentary session. This will:

- Make our governing Council independent from the regulators
- Give all regulators smaller, independently appointed governing Councils, with the aim of having a majority or parity of public members
- Enable us to carry out the new responsibilities proposed in the White Paper. These new responsibilities include the audit of the early stages of the fitness to practise

[122] General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

process[123] of the regulators, and monitoring the GMC's new power to appeal decisions of the new Independent Adjudicator
- Create a new body to undertake independent adjudication
- Introduce for all regulators a requirement to use the civil standard of proof, flexibly applied, rather than the criminal standard
- Enable the revalidation of doctors by ensuring that all healthcare organisations employing or contracting with doctors appoint a 'responsible officer' with personal responsibility to work with the GMC to identify and handle cases of poor professional performance.

CHRE comments on these proposals

We welcome the White Paper *Trust, Assurance and Safety*, and specifically:

- **The proposal that we should have a smaller Council, with all members independently appointed, which will no longer include members nominated by the regulators.** The Government sees CHRE as '*an authoritative independent voice for patients on the regulation of professionals, providing expert advice on policy*'. The composition and appointment of the members on our Council will enable us to be this independent voice on regulation.
- **The introduction of the civil standard of proof, flexibly applied, rather than the criminal standard** for all regulators. This is consistent with the focus of regulation on the public interest, but keeps the balance right with fairness to registrants.
- **The Government's intention to enable revalidation for doctors, as we strongly support the introduction of revalidation for all regulated health professions.** The public are entitled to expect that healthcare practitioners remain competent and safe to practise throughout their professional career.
- **More independent adjudication of fitness to practise cases across regulatory bodies.** The Bill will establish an Independent Adjudicator which will adjudicate on cases about doctors, establish a central list of panellists for the other health professions, and may over time carry out adjudication for other professions. We believe that public protection and confidence in regulation will be enhanced by consistent fitness to practise processes for all professions. We expect the procedures of the new body and those of the other regulators to be harmonised over time.

However, we are concerned that the Bill does not enable some of our new responsibilities proposed by the White Paper. We recommend that:

- **The Bill should amend our Act to enable us to carry out the audit of the cases that the regulators have not taken to full fitness to practise panels.** We welcome the new power to audit the preliminary stages of the fitness to practise process. However, sub-section 26(3) of our Act currently prevents CHRE doing anything about the case of an individual at the preliminary stages of the fitness to practise process, and therefore would prevent this audit.

[123] All regulators have processes to deal with serious concerns about the fitness to practise of their registrants, which enable them to remove or restrict registrants' right to practise. There is no single definition of fitness to practise applying to all regulators. Overall, a health practitioner who is fit to practise is safe and competent to treat patients.

- **The Bill should enable exchange of information with the new Independent Adjudication Body**, to enable CHRE to monitor GMC's appeals of the Independent Body decisions.

Number 2: Changes to the objective and role of CHRE

The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[124]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

Trust, Assurance and Safety and the Health and Social Care Bill

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

The objective and role of CHRE

The White Paper sees CHRE as '*an authoritative independent voice for patients on the regulation of professionals, providing expert advice on policy*' (paragraph 1.25). To implement this vision of CHRE, the Health and Social Care Bill introduces several changes: changes to the constitution of the Council, amendments to our mission, and adding a duty to inform and consult the public.

Changes to the constitution of our Council

The Health and Social Care Bill introduces a new governing Council for CHRE of nine members, all independently appointed. This replaces our current Council of 19 members, with ten lay members, and nine members nominated each by one of the regulators of health professionals.

We fully support the proposal that we should have a smaller Council, with all members independently appointed, which will no longer include members nominated by the regulators. The composition and appointment of the members on

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[124] General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

our Council will enable us to be the independent voice on regulation proposed by the Government.

Additional objective

The Bill also adds to our mission the main objective of promoting the health, safety and well-being of patients and members of the public. The aim of this amendment is to bring our statutory purpose in line with that of the regulatory bodies.

We welcome the addition of this new objective to our Act, but are concerned that the Bill does not include the focus on protection of the public:

- We fully support consistency of objectives between CHRE and regulators. However, the Bill does not replicate the precise wording of the objective set for the regulators, which is described in recent amendments to their legislation as 'to protect, promote and maintain the health, safety and well-being of members of the public' and patients.

- We believe that public protection should be part of this new statutory objective. Protecting the public has been, and should continue to be, our primary focus, and where we can add most value to the safety and quality of the UK healthcare system.

Consulting and informing the public

The Bill finally requires us to consult and inform the public. We already see consulting and informing patients and the public as an integral part of our current responsibilities to promote excellence in regulation, and of our strengthened role on best practice and common regulatory issues. We are currently **actively preparing for the implementation** of this new duty.

Legislative background

The Health and Social Care Bill amends the National Health Service Reform and Health Care Professions Act 2002, which establishes CHRE.

Clause 106 amends schedule 7, which sets the constitution of our Council.

Clause 105 (3) amends section 25, which sets the responsibilities of CHRE

Clause 108 amends section 26, which sets the powers and duties of CHRE in general. It adds a new section requiring CHRE to inform and consult with the public.

Number 3: Power for CHRE to audit cases that the regulators have not taken to full fitness to practise panels

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The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[125]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

The new power of audit for CHRE

Our current legislation does not enable us to undertake the audit role envisaged by the White Paper, and needs to be amended by the Health and Social Care Bill.

The White Paper *Trust, Assurance and Safety* states that "*the Government will ask CHRE to review a sample of cases that the regulators have not taken to full fitness to practise panels"* (the 'audit') (paragraph. 4.16).

We fully support this proposal, as the external audit of cases at the preliminary stages of the fitness to practise procedure will contribute to patient safety:

- Fitness to practise panels protect public safety by determining whether professionals are fit to practise and if not, whether they should be barred from practising their profession, or should only practise with restrictions on what they can do. Out of all the complaints received by regulators, it is therefore essential that the right cases reach the fitness to practise panels.

- External audit can contribute to the continuous improvement of regulatory functions. We are confident that our work in reviewing the final outcomes of competence and

[125]General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

conduct cases[126] has been a major factor in generating improvements in the quality of outcomes from the regulators' fitness to practise panels, through learning from cases referred to Court and the feedback we have been able to give to regulators.

- External audit also enhances the transparency and accountability of the procedures.

However, a part of our existing legislation would prevent us from undertaking the role envisaged for CHRE in the White Paper. We recommend that the Health and Social Care Bill should amend our current Act to enable our proposed audit role:

- Section 26(3) of our Act states that CHRE *may not do anything* in relation to the case of any individual where there are, will or have been proceedings before the regulator or an allegation has been made that could result in proceedings, even if the case has been closed.

- Our legal advice is that this section prevents us from undertaking the audit of cases which the regulators have not taken to full fitness to practise panels.

- Another section of our Act, section 26(4), allows exceptions to the prohibition imposed by section 26(3).

- Our Act could be amended to enable the proposed audit by adding a new section, 29A, which would specify CHRE's audit function, and amending s26(4) to include this new section 29A. This would lift the prohibition in s26(3) in relation to our new audit power. This would also preserve the role of s26(3) in preventing CHRE to have a role in relation to on-going cases.

Legislative background

The National Health Service Reform and Health Care Professions Act 2002 gives CHRE a wide remit of doing anything it believes is necessary or expedient to fulfil its functions under section 26. However, this is restricted by section 26(3), which prevents CHRE to have a role in relation to on-going cases, except in specific instances listed in section 26(4). Section 26 reads:

(1) Except as mentioned in subsections (3) to (6), the Council may do anything which appears to it to be necessary or expedient for the purpose of, or in connection with, the performance of its functions.

(2) The Council may, for example, do any of the following-
  (a) investigate, and report on, the performance of each regulatory body of its functions;
  (b) where a regulatory body performs functions corresponding to those of another body (including another regulatory body), investigate and report on how the performance of such functions by the body in question compares;

[126] We currently have a power to review the conduct and competences cases which have been considered by the fitness to practise panels, and where we consider that a case is unduly lenient and that it is necessary for the protection of the public, we can refer the case to Court (our 'section 29' power).

(c) recommend to a regulatory body changes in the way it performs any of its functions.

(3) The Council may not do anything in relation to the case of any individual in relation to whom-

(a) there are, are to be, or have been proceedings before a committee of a regulatory body, or the regulatory body itself or any officer of the body;
(b) an allegation has been made to the regulatory body, or one of its committees or officers, which could result in such proceedings.

(4) Subsection (3) does not prevent the Council from taking action under section 28 or 29, but action under section 29 may be taken only after the regulatory body's proceedings have ended.

Number 4: CHRE review of the GMC's right of appeal from the Independent Adjudication Body

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The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[127]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

CHRE review of the GMC's right of appeal

We would like to see a requirement to exchange information in the Health and Social Care Bill in order to review the GMC's right of appeal against the decisions of the new Office of the Health Professions Adjudicator (the 'Independent Adjudicator').

[127] General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

The White Paper states that "as part of its scrutiny function, CHRE will review the application of this new GMC right of appeal" against the decisions of the new Independent Adjudicator, "reporting to Parliament on an annual basis" (paragraph 4.36).

The Bill will enable the establishment of a new Office of the Health Professions Adjudicator for doctors and opticians. The GMC will no longer adjudicate on fitness to practise cases through independently appointed panels. This reform will also remove our power to appeal the final outcomes of competence and conduct cases when we consider that they are unduly lenient and that it is necessary for the protection of the public. Instead, the GMC will have a right to appeal against the decisions of the Independent Adjudicator.

We fully support the proposal that we will review the application of the new GMC's right of appeal:

- External review can contribute to the continuous improvement of regulatory functions. We have considerable experience in reviewing relevant competence and conduct cases. We believe we can use this experience to work with the GMC to contribute to patient safety.

- External review enhances the transparency and accountability of the fitness to practise procedures. It reinforces public confidence in regulation by assuring the public that the rights cases are appealed.

However, to carry out this review power, the Bill needs to enable exchange of information with the Independent Adjudicator.

To monitor GMC's appeals, we will need information on cases from the Independent Adjudicator. To enable information exchange, it would be helpful if there were a requirement that the Independent Adjudicator must co-operate with CHRE in the exercise of its functions. Such a requirement already applies to the regulators under s27 (1), and could include the Independent Adjudicator.

Legislative background

The National Health Service Reform and Health Care Professions Act 2002 states under s27(1): *"Each regulatory body must in the exercise of its functions co-operate with the Council."*

Number 5: Duty of CHRE to report on the performance of the regulators of health professionals introduced by the Health and Social Care Bill

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The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[128]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

Duty to report on the performance of the regulators

In particular, the Bill will introduce a duty for CHRE to report in its Annual Report how far, in its opinion, each regulatory body has complied with any duty imposed on it to promote the health, safety and well-being of patients and the public. The new clause links two of our current duties and powers: our power to monitor and report on the performance of the regulators, and our duty to report annually on the exercise of our functions.

- **We welcome this duty, because it will make the regulation of healthcare professionals more transparent and accountable to Parliament and the public.** We believe this will contribute to patient confidence and patient safety as it will enable regulators to demonstrate how they protect the public and how they can, and do, drive up their performance in doing so.

- **We are actively preparing for the implementation of this new duty.** We want to assure ourselves that the performance review process we use is fit for purpose. We aim for our performance review process to be robust, fair, transparent, proportionate and add value to regulation. We are currently developing a new standards-based performance review process, which we will pilot and consult on, for introduction in the next financial year.

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[128] General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

Legislative background

This new duty is introduced by amending schedule 7, paragraph 16 (1) of the National Health Service Reform and Health Care Professions Act 2002, which requires CHRE to prepare a report on the exercise of its functions during each financial year. Paragraph 16 (2) then requires CHRE to lay a copy of its report for that year before Parliament, the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly.

Currently, CHRE already has the power to review the performance of the regulators. Under s26 (2), CHRE can:

> (a) investigate, and report on, the performance by each regulator of its functions,
> (b) investigate and report on how the performance of corresponding functions by different regulators compares
> (c) recommend to a regulator changes in how it performs its functions.

Number 6: Extending CHRE's power to review and appeal conduct and competence cases to health cases

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The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[129]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

The power to review health cases

We currently have the power to appeal the final outcomes of the conduct and competence cases of all the regulators, if we consider that they are unduly lenient and

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that an appeal is necessary for the protection of the public. Health cases are currently excluded from this appeal power (our 'section 29 power').

We support the Health and Social Care Bill extension of CHRE's current power to appeal conduct and competence cases to health cases. We believe this will ensure better protection of patient safety:

- Health cases can pose a similar risk to patient safety as conduct and competence cases. The focus on rehabilitation may lead to fewer health cases being referred to regulators, but this is also likely to mean that a higher proportion of those cases will be very serious.

- External audit can contribute to the continuous improvement of decision-making in health cases. We are confident that our work in reviewing the final outcomes of competence and conduct cases has been a major factor in generating improvements in the quality of outcomes from the regulators' fitness to practise panels, through learning from cases referred to Court and the feedback we have been able to give to regulators. We should promote consistency and learning across regulators in all types of cases.

- Regulation is concerned with the concept of fitness to practise in the round: whether a professional's fitness to practise is impaired for reasons of performance, conduct or health, or a combination of factors. The fitness to practise processes also focus on the risk of harm to patients and the public, rather than punishment.

- Due to our focus on public protection, we need to satisfy ourselves that regulators have proper processes in place when considering health cases. Health cases represent a smaller but important part of the fitness to practise workload for the regulatory bodies[130].

- We fully support the need to handle cases of ill health with sensitivity and the focus of the White Paper on support and rehabilitation of professionals. We believe this is compatible with the extension of our review power, which is solely focused on cases of undue leniency.

Legislative background

The National Health Service Reform and Health Care Professions Act 2002 gives CHRE a power to appeal 'relevant decisions' of the fitness to practise process. Relevant decisions are the final outcomes of competence and conduct cases. The Act defines relevant decisions by listing the panels or committee which reach relevant decisions in section 29 (1).

The Health and Social Care Bill amends section 29 (1) with clause 109. Clause 109 lists the committees which reach relevant decisions, and adds the health committee of the

[130] Looking at the regulators with the highest numbers of cases, 28% of NMC cases and 43% of GMC cases were health cases, in 2005/6 and 2005 respectively. Between 2002/03 and 2004/05, 20% of cases referred to the National Clinical Assessment Service presented concerns with the health of the doctor or the dentist.

regulators (except the GMC and GOC, whose adjudication function is transferred to the OHPA).

Number 7: Supporting revalidation

The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[131]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

Revalidation

Revalidation is described as 'a mechanism that allows health professionals to demonstrate that they remain up to date and fit to practise.' The White Paper supports the principle of revalidation and proposes its implementation for doctors and all other health professions.

The White Paper proposes to build on appraisals, staff management, clinical governance and other existing mechanisms to implement revalidation and, where such systems do not exist or need to be complemented, on more direct arrangements with the regulator.

For doctors, the White Paper describes a system with two components. Relicensing will apply to all doctors who want to continue practising medicine, and will indicate that a doctor is licensed to practise. Recertification will only apply to doctors on the specialist or GP registers. Doctors will need to show that they continue to meet the standards applying to their specialty.

A key feature of the proposed system for doctors is the establishment of a network of GMC affiliates in England. GMC affiliates would 'bridge the gap' between local and national regulation of doctors. GMC affiliates are intended to support local employers in

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[131] General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

handling concerns about doctors and devising measures to help doctors return to fitness to practise, and to provide assurance that relicensing procedures are fit for purpose. Medical directors, and others in similar roles, will take on the role of more local GMC affiliates, called responsible officers. The White Paper recognises that the practicalities need to be piloted first and a working group has been set up to co-ordinate and pilot processes for medical revalidation.

The Health and Social Care Bill aims to support the revalidation of doctors by ensuring that all healthcare organisations employing or contracting with doctors identify a 'responsible officer' with responsibilities relating to the evaluation of fitness to practise of doctors.

For other health professionals, work on revalidation is at an earlier stage of development. The White Paper recognises that "the intensity and frequency of revalidation needs to be proportionate to the risks inherent in the work in which each professional is involved". A second working group, co-ordinated by CHRE, has been established to develop and co-ordinate proposals for non-medical revalidation.

We support in principle the introduction of revalidation for all regulated health professions:

- The public are entitled to expect that healthcare practitioners remain competent and safe to practise throughout their professional career. We support the dual objectives outlined in the White paper for revalidation of providing assurance of performance and encouraging continued competence, and identifying problems and opportunities to put them right.

- The most important issue facing employers, professionals, regulators and others is how to implement revalidation. In general, there is support for the concept of revalidation across regulators, but it is important that the implementation benefits patient safety, is proportionate and flexible, and considers carefully the resource implications.

- Specifically, we support the objective of the responsible officer of improving the interface between local and national regulation. Effective systems of local regulation by employers and others are integral to revalidation processes and improving the handling of concerns about doctors at local and national levels.

Legislative background

Clause 110 of the Health and Social Care Bill amends the Medical Act 1983. It will enable a requirement for local organisations to nominate or appoint a responsible officer with responsibilities relating to the evaluation of fitness to practise of medical practitioners.

Number 8: Adoption of a common civil standard of proof for the regulators of health professions

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The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[132]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

The common civil standard of proof

We support the introduction in the Health and Social Care Bill of the civil standard of proof for all regulators. This is consistent with the focus of regulation on public safety but keeps the balance right with fairness to registrants.

The White Paper *Trust, Assurance and Safety* states that '*the Government agrees …that the civil standard of proof, with its sliding scale, should be the common standard of proof for all the regulatory bodies in fitness to practise proceedings*' (paragraph. 4.8).

Currently, most regulators of health professionals use the civil standard. This proposal would put the standard of proof on a statutory basis for all regulators and introduce the civil standard for the GMC, the GOC and the NMC.

The issue

The difference between civil and criminal standard of proof refers to the level of certainty that must be achieved to prove disputed facts. The criminal standard of proof requires the panel to be wholly convinced that facts are proven, 'beyond reasonable doubt'. The civil standard requires the panel to be persuaded that the facts are more likely than not to be true: the facts need to be proven 'on the balance of probabilities'.

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[132]General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

There is a perception amongst some professionals that the use of the civil standard could lead to harsher decisions against professionals. However, the standard of proof applies only to one part of the decision-making process. When deciding on a fitness to practise case, the panel will consider three issues in turn:

- Whether the alleged facts are found proved
- Whether the facts proved amount to impaired fitness to practise
- What should be the sanction imposed, if any.

The standard of proof is only applied at the first stage, in determining whether alleged facts are found proven or not proven, when facts are disputed.

In addition, the civil standard of proof can be flexibly applied. This means that the more serious the allegation and its consequences, the stronger the evidence needs to be to prove the allegation. The White Paper notes that there is clear legal authority that, in cases of sufficient gravity, the civil standard of proof, flexibly applied, is virtually indistinguishable from the criminal standard. The GMC is already consulting on the implementation of the civil standard, and the NMC agreed in its response to the reviews on the regulation of health professions that it would be an appropriate time to move to using the civil standard.

Our position

We support the introduction of the civil standard of proof for all regulators:

- The introduction of the civil standard is consistent with the focus of regulation on public safety. The fitness to practise process is intended to be protective for the public rather than punitive for the registrant. The key questions are whether a professional's fitness to practise is impaired, and how to protect the public. The civil standard is used in other proceedings focusing on public protection, for instance child protection proceedings, employment tribunals, and mental health review hearings.

- Regulators should adopt the standard of proof that makes it easier to consider whether there is a question of public protection. The civil standard means that, for less serious cases, the facts of the case are more likely to be found proved than under the criminal standard. This could mean that more cases are referred to the adjudication panels for consideration. We believe that replacing the criminal standard of proof by the civil standard will mean that more health professionals enter the formal adjudication procedures.

- However, the civil standard strikes the right balance with fairness with registrants. The flexible interpretation of the civil standard of proof means that in practice, for serious cases, there is little difference between the civil and the criminal standards.

In addition:

- The civil standard of proof is more likely to contribute to public confidence in regulation.

- The introduction of the civil standard is practically feasible. Most of the regulators of health professionals use a civil standard of proof, and there is therefore evidence that it can be applied in fitness to practise cases.

- We support greater consistency in the fitness to practise procedures of the nine regulators where this is appropriate. We believe that this allows sharing of learning between regulators, is clearer to patients and the public, and fairer to registrants.

Legislative background

The Health and Social Care Bill amends section 60 of the 1999 Health Act through clause 104 to introduce the civil standard of proof to all fitness to practise proceedings. This will apply to the proceedings of all the regulators and the new Office of the Health Professions Adjudicator.

Number 9: Establishing more independent adjudication of fitness to practise cases across regulators - the Office of the Health Professions Adjudicator

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The current role of CHRE

The Council for Healthcare Regulatory Excellence (CHRE) is the overseeing body for the nine regulators of healthcare professionals in the UK[133]. Our current primary purpose is to promote the interests of the public and patients in relation to the regulation of healthcare professionals. Our responsibilities are set out in the National Health Service Reform and Health Care Professions Act 2002. We carry out these responsibilities by working in partnership with the regulators. We can review the performance of the regulators, monitor and refer cases of 'undue leniency' to court (our 'section 29' jurisdiction), and advise health ministers.

***Trust, Assurance and Safety* and the Health and Social Care Bill**

The Government proposes new arrangements for the regulation of health professions in its White Paper *Trust, Assurance and Safety*. The Government intends to implement some of these arrangements in the Health and Social Care Bill, in this parliamentary session.

The Office of the Health Professions Adjudicator

We support the move towards more independent adjudication of fitness to practise cases across regulators. We expect the procedures of the new adjudicator and of the regulators to be made more consistent over time. This would include, for instance, similar sanctions available to adjudication panels.

[133]General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), and Royal Pharmaceutical Society of Great Britain (RPSGB).

The Health and Social Care Bill will establish the Office of the Health Professions Adjudicator (OHPA), as proposed by the White Paper (paragraphs 4.36-4.37). The proposed OHPA will adjudicate on cases about doctors and, as requested by the General Optical Council, opticians.

For other regulators, the Government also proposes that OHPA will establish a list of vetted and approved panellists for all adjudication panels. Regulators will be able to draw on this list in order to undertake independent adjudication. The White Paper states that over time, other regulators may wish to adopt the independent body to provide further assurance of independence to the public.

Independent adjudication is in line with the recommendation of Dame Janet Smith in the Fifth Report of the Shipman Inquiry that the adjudication function of the GMC should be separated from the GMC's other functions.

Independent adjudication can be undertaken by a new, separate body, or by panels which are independently appointed and trained by a separate organisation. The proposed system is a mixture of both approaches: an independent body for doctors and opticians, as well as a list of panellists on which other regulators can draw.

We support the move towards more independent adjudication of fitness to practise cases across regulators.

- There is a concern that the regulator should not be both prosecutor and judge, in line with the principles of modern practice and the principles of the Human Rights Act 1998, which establishes the entitlement to a fair and public hearing "*by an independent and impartial tribunal established by law*".

- Independent adjudication can provide re-assurance to the public that adjudication is fair and focuses on public protection. We have no reason to believe that, overall, the current fitness to practise procedures of the regulators are biased towards registrants[134]. However, we believe that fitness to practise panels should not only be, but also seen to be, unbiased in favour of registrants. This can be achieved by separating adjudication entirely from the other functions of the regulators.

- An independent tribunal will also increase "*public accountability of judgements about a doctor's registration"*, as noted by the Chief Medical Officer in *Good doctors, safer patients*, as its members will be publicly appointed.

We expect the procedures of the new body and those of the regulators to be harmonised over time, where appropriate:

- Harmonisation can help dissemination and implementation of good practice as the best system can be adopted for all. Greater consistency also maximises the potential for inter-regulator learning and benchmarking

[134] We can appeal the final outcomes of conduct and competence cases when we consider that they are unduly lenient and that it is necessary for the protection of the public. The number of cases we referred to Court has decreased from ten in 2004/5 to four in 2006/7, while the number of relevant cases has increased from 590 to 915.

- Harmonisation also promotes greater clarity of the fitness to practise procedures across regulators for patients, the public and employers. The current variation both in the powers of regulators to impose sanctions and in the terminology they employ is potentially confusing to the public and others

- Greater consistency where appropriate can lead to greater fairness to registrants, as the way that cases are handled and determined would be less dependent on the particular profession.

Legislative background

Clauses 91-102 and schedules 6 and 7 of the Health and Social Care Bill establish a new Office of the Health Professions Adjudicator and amend the Medical Act 1983 and the Opticians Act 1989.

Clause 102 (3) requires the OHPA to consult with key stakeholders, including CHRE, before making rules.

Further information

Please contact Elisa Pruvost, Policy Manager, CHRE, 11 Strand, London WC2N 5HR, on elisa.pruvost@chre.org.uk or 020 7389 8038.

November 2007

General Medical Council

Health and Social Care Bill Second Reading Briefing from the General Medical Council

Overview

The GMC welcomes the publication of the Health and Social Care Bill as a further step towards implementation of the White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century.* The proposals we published in November 2006, which are reflected in the White Paper, provide the basis for a strong, independent and accountable system of health professional regulation into the foreseeable future.

A number of provisions in the Bill relate specifically to the GMC and its work:

- Office of the Health Professions Adjudicator – the GMC is committed to working with the Government to ensure a smooth transition to an independent adjudication body, subject to a satisfactory agreement on the details (Clauses 91-102, Schedules 6-7).

- We welcome the placing of GMC sanctions guidance onto a statutory footing as this reinforces the GMC's ownership of professional standards for the medical profession (Schedule 7).

- We welcome the introduction of a statutory right for the GMC to appeal against decisions of OHPA, reflecting our continuing responsibility for the fitness for purpose of the medical register and the fitness to practise of those on it (Schedule 7).

- The requirement to adopt the civil standard of proof is consistent with the decision the GMC has already taken and with the practice of the majority of other health care regulators (Clause 104).

- Responsible Officers – the GMC welcomes the strengthening of local clinical governance systems. Effective local systems will be vital for the delivery of a robust system of revalidation for doctors (Clauses 110-119).

The GMC's approach

Independent adjudication

The GMC published a package of proposals in 2006 designed to deliver a modern framework of independent and accountable medical regulation. The White Paper reflected those proposals.

The GMC believes that patients' interests are best served by independent, accountable regulation. The GMC must be independent of government as the dominant provider of healthcare in the UK; independent of domination by any single group; and be publicly accountable to Parliament for the discharge of its functions.

We are confident that our current arrangements for adjudication lead to consistent and high quality decisions. Nevertheless we accept the Government's decision to establish an independent adjudication body and will use our expertise to help ensure a smooth transition to it. We are pleased that the Government has accepted our view that the GMC should have a right of appeal against the adjudicator's decisions. We welcome the statutory footing the Bill gives to our sanctions guidance. This makes it clear that the GMC remains the owner of professional standards and protects in legislation the relationship between OHPA and the GMC in the application of the principles of *Good Medical Practice*.

The civil standard of proof

Our 2006 proposals also included support for the introduction of the civil standard of proof.

GMC President Sir Graeme Catto is on record as saying he does not believe that the change will result in more doctors being erased from the register. But it should mean it is easier to impose appropriate restrictions on a doctor's practice where that is necessary to protect patients.

Removing a doctor from the register is very serious; and where the consequences are a loss of livelihood, the rigour of the criminal standard of proof, or a standard close to it, is

clearly appropriate. On the other hand, the consequences of sanctions other than erasure may be less profound and this can be taken into account in the evidence required to reach a finding on the civil standard of proof. This approach is wholly consistent with protecting patients and the public interest, and with being fair to doctors.

The standard of proof applicable in criminal proceedings is proof beyond reasonable doubt; conventionally, juries are directed by judges not to convict unless they are sure of a defendant's guilt. In civil proceedings, the standard of proof is proof on the balance of probabilities; a fact will be established if it is more likely than not to have happened.

The legal advice we have received makes it clear that the civil standard of proof is not a rigid criterion by which facts are to be judged. It is to be tailored to the facts of any given case. It is often said that the more serious the facts alleged, the more cogent and compelling will be the evidence required.

We believe that the application of the civil standard of proof more accurately reflects the true function of a GMC Fitness to Practise panel. The panel is not a criminal court and it is not applying the criminal law. In particular, we concluded that it is questionable whether it is appropriate to retain the criminal standard of proof in a protective, rather than criminal jurisdiction, especially when the concerns relate to a doctor's heath or performance.

The great majority of professional tribunals in various walks of life apply the civil standard of proof. The civil standard of proof is already used by the majority of other healthcare regulators. During our recent consultation, a number of other regulators that apply the civil standard of proof confirmed that it did not present them with any undue difficulties. The Court of Appeal has recently explained that the use of the criminal standard of proof in areas other than the criminal law is very much the exception.

We are committed to ensuring that our procedures are fair, objective, transparent, free from unfair discrimination and that they command the confidence and support of all those who receive and provide healthcare across the UK.

We believe that the application of the civil standard of proof is consistent with protecting patients and the public interest and is, at the same time, fair to doctors.

Governance

The GMC's model of governance is that there should be parity between medical and lay members without an inbuilt majority on the Council for either. We should aim for an equal proportion of medical and lay Council members, with 50% medical and 50% lay.

The GMC should have a balanced composition that is reflective of those who receive and provide healthcare across the UK – patients and the public; doctors; the NHS and other healthcare providers; the medical schools and medical royal colleges.

The GMC's governance lies outside the scope of the Bill, but we understand that the Government will shortly bring forward a draft Order under Section 60 of the Health Act 1999 to implement the GMC's parity model.

Responsible officers and local regulation

The GMC fully endorses the need for greater coherence and coordination across all levels of medical regulation and in particular the local component. Healthcare providers have a clear responsibility for effective clinical governance arrangements that ensure the fitness for purpose of those whom they employ or contract with to provide services.

There also must be effective channels of communication between national and local systems. This includes creating clarity about those matters that need to be addressed locally and those that should be dealt with by the national regulator.

The establishment of 'responsible officers' at a local level means that for the first time there will be a nominated individual at a local level who will have a statutory responsibility for fitness to practise matters.

We also welcome the clear distinction between the roles of responsible officers and those of the GMC. Responsible officers will be locally employed and not be employees of the GMC. Their appointment will strengthen local arrangements and is not an extension of the GMC's powers to the local level

For further information please contact:

GMC Public Affairs
020 7189 5394
publicaffairs@gmc-uk.org

General Optical Council

A. GOC welcomes Health and Social Care Bill

Fri 16 Nov 2007
GOC welcomes Health and Social Care Bill

The General Optical Council (GOC) has welcomed the publication of the Health and Social Care Bill, particularly the creation of the new Office of the Health Professions Adjudicator (OHPA) to hear 'fitness to practise' (disciplinary) cases referred by the health professional regulators.

At its meeting in June, the GOC gave its formal support to transferring responsibility for hearings to the OHPA at the earliest opportunity. Rosie Varley, chairman of Council said: "The move to an independent adjudication body is in line with best practice to ensure that registrants' human rights are protected and that all parties can continue to expect fair, impartial treatment. In the longer term, shared adjudication should mean more consistent fitness to practise decisions across the healthcare professions."

The Council meets next week in Edinburgh, where members will discuss the implications of the Bill and other Government proposals for reforming healthcare professional regulation.

ENDS

For further information please contact:
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t: 020 7307 3472
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About the General Optical Council:
The GOC is the regulator for the optical professions in the UK. Its purpose is to protect the public by promoting high standards of education and conduct amongst opticians. The Council currently registers around 22,000 optometrists, dispensing opticians, student opticians and optical businesses.

NOTES
1. The General Optical Council (GOC) will meet on 22 November at the Radisson SAS Hotel, Edinburgh. Journalists and members of the public who would like to attend should contact: lkennaugh@optical.org.

2. The Council takes action if we receive a complaint that a registrant's fitness to practise may be impaired due to:

- misconduct
- deficient professional performance
- a caution or conviction in relation to a criminal offence
- physical or mental health problems
- a finding of impaired fitness to practise by another regulatory body

If, after investigation, there is a case to answer, it will be referred to a public hearing of the Fitness to Practise Committee (a 'fitness to practise' hearing). The GOC has already separated its role in investigation and prosecution from adjudication by creating an independent hearings panel.

General Osteopathic Council

General Osteopathic Council
Media Release

General Osteopathic Council comments on new measures to enhance patient safety

Friday, 16 November 2007 – the General Osteopathic Council (GOsC) today commented on the Government's new Health and Social Care Bill. GOsC Council Chief Executive & Registrar, Madeleine Craggs, said: "Maintaining public confidence in osteopathic regulation and development is key to the work of the GOsC. For this reason we support proposals, such as sharing information, between the Regulatory Bodies, regarding concerns about the conduct and performance of healthcare workers. This will better protect patients and the public." With regard to the creation of a new independent adjudicator – the Office of the Health Professions Adjudicator, Craggs continues: "Within the GOsC, our experience is that professional members of Council are often the harshest critics when adjudicating over their colleagues. However, we appreciate that the public need to see greater transparency and independence across all bodies overseeing the regulation of health professionals. Indeed to this end, the GOsC has always used a Lay Member to chair its adjudication panels and has utilised fully its power, under existing legislation, to co-opt independent members to its fitness to practise committees." The General Osteopathic Council will be working to ensure these changes have the confidence of osteopathic patients and the buy-in of the profession itself.

For further information, please contact:
The GOsC Press Office
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NOTES TO EDITORS
The General Osteopathic Council
The General Osteopathic Council (GOsC) exists to protect patients by promoting excellence in osteopathic care. The GOsC regulates, develops and promotes the profession of osteopathy by:

- Maintaining the definitive Register of those who have satisfied the GOsC that they can practise osteopathy safely and competently.
- Defining and maintaining high standards of education, training and clinical practice.
- Guiding osteopaths in standards of professional practice.
- Dealing promptly and effectively with osteopaths whose competence or fitness to practise is called into question.
- Promoting and developing the profession and practise of osteopathy.

The Statutory Register of Osteopaths

- Osteopaths are statutorily regulated health professionals and form an integral part of primary care teams.
- There are currently **3,981** osteopaths on the UK Statutory Register.
- The General Osteopathic Council (GOsC) regulates, promotes and develops the osteopathic profession, maintaining a Statutory Register of those entitled to practise osteopathy in the United Kingdom.
- Only practitioners meeting the highest standards of safety and competency are eligible for registration. Proof of good health, good character and professional indemnity insurance cover is also a requirement.

- It is an offence for anyone to describe themselves as an osteopath and practise as such, unless registered with the GOsC. The public can, therefore, be confident in visiting a registered osteopath that they will experience safe and competent treatment from a practitioner who adheres to a strict Code of practice:
- *"13. (1) The General Osteopathic Council shall from time to time determine the standard of proficiency which, in its opinion, is required for the competent and safe practice of osteopath"* (Osteopaths Act 1993).
- Copies of Standard 2000 (S2K) are available from the GOsC on 020 7357 6655.
- *"Any patient consulting an osteopath is entitled to a high standard of care. The register of osteopaths exists so that members of the public can identify those who have demonstrated their ability to practise to the required standards*" (extract from the GOsC 'Code of practice', GOsC, 2005).
- Copies of the Code of Practice are available from the GOsC on 020 7357 6655.
- The **2007 Statutory Register of Osteopaths** provides a geographical index of all practising osteopaths, and is available to healthcare providers and the general public. Printed copies are available from the GOsC. A current and searchable listing of osteopaths is available on the GOsC website: www.osteopathy.org.uk.

About Osteopathy

- Osteopathy uses many of the diagnostic procedures involved in conventional medicalassessment and diagnosis. Its main strength lies in the unique way the patient is assessed holistically from a mechanical, functional and postural standpoint. Treatment is aimed at improving mobility and/or reducing inflammation by using gentle manual osteopathic techniques on joints, muscles and ligaments.
- Patients are given positive advice, related to their lifestyle, about how they use their body. Age is no barrier to osteopathy since each patient is assessed individually and treatment is gentle.
- Osteopaths treat a wide range of conditions, including changes to posture in pregnancy; infantile colic or sleeplessness, repetitive strain injury, postural problems caused by driving or work strain, glue ear in children, the pain of arthritis and sports injuries, amongst others.

Health Professions Council

The Health Professions Council welcomes the publication of the Health and Social Care Bill. As a statutory regulator, our primary function is to protect the health and well-being of people using the services of health professionals registered with us.

We support the adoption of the civil standard of proof for fitness to practise procedures for all regulators. We currently use the civil standard of proof in our procedures and find it to be a useful, fair and proportionate way of conducting fitness to practise proceedings. This move represents a positive step that will help to harmonise fitness to practise procedures across the healthcare regulators.

We believe that the Bill will strengthen measures for public protection and look forward to working with the government to achieve the implementation of the proposed changes.

For further information please contact:

Charlotte Urwin, Policy Officer, charlotte.urwin@hpc-uk.org or 020 7840 9126
Nina Blunck, Public Affairs Manager, nina.blunck@hpc-uk.org or 020 7840 9132

Local Government Association

Councils are ready to tackle future health challenges, but must have the powers and resources necessary to provide the care people expect and deserve.
By 2009, there will be over 400,000 more older people, many of whom will require social care. Without additional funding, local government may potentially face a situation where it cannot afford to provide support to 370,000 people with lower level of need and who would currently receive care.
This is not a situation older people and their families expect or deserve. There is a strong and compelling argument for ministers to place a greater emphasis on preventative services. This would make the available money go further, provide better value for the taxpayer and help to improve the health of the nation.

1. LGA key messages on the Health and Social Care Bill, published on Friday:

- **The Care Quality Commission must support councils' ambitions for their areas.** The new integrated regulator is a positive step, but the CQC must work within t he new local government performance framework, must recognise councils' accountab ility for setting a vision for each area, and must carefully manage three-way relationships between itself, councils and NHS providers in areas of joint provision

- **Councils support the regulation of professional standards in improving outcomes for local people.**
  We believe that any enhancement of professional accountability, whatever the profession, to strengthen protection of individuals is a positive move which will im prove service standards.

- **Councils must have the powers they need to protect the people they serve from contamination and infection.**
  While proposed changes to public health legislation are mainly sensible, we are concerned that passing powers from local authorities to Justices of the Peace will increase bureaucracy and create new inancial burdens for councils seeking to pr otect the public from infection and contamination.

2. Summary of government proposals:

- The bill will create the Care Quality Commission, a new health and adult social care regulator. It will be equipped with new powers, backed by fines, to intervene where hospitals fail to meet hygiene standards. Further details will be set out following the completion of the Government's consultation on healthcare regulation.

- There will be a strengthened approach to infectious diseases and contamination, updating legislation to take into account scientific and international developments. It also provides for a one-off payment to expectant mothers.

- It will implement, following the inquiry into the case of Harold Shipman, the Gover nment's manifesto commitment to strengthen clinical governance and to ensure professional activity is more accountabl to the public.

Further information
For further information on this briefing, please contact Andy Taylor in LGA Public Affairs at andy.taylor@lga.gov.uk or 020 7664 3334.

Part 1 -The Care Quality Commission

Key Proposals

- Establishes the Care Quality Commission (CQC) in England –
the new integrated regulator for council social care services and the NHS

- The CQC will merge existing regulators –
the Commission for Social Care Inspection (CSCI), Healthcare Commission and the Mental Health Act Commission

- The CQC will register, review and inspect health and social care services in England; registration will extend to NHS providers for the first time. The focus will be on assuring patients and service users of the safety and quality of local care services

- The CQC will have a wider range of powers than its predecessor organisations as well as flexibility regarding how and when theycan be used. Enforcement tools will include the power to issue penalty notices and to suspend registration

- The CQC will report on the efficiency and economy of council and NHS provision and commissioning

- The CQC will publish a code of practice that it will follow for its dealings with confidential personal information

LGA View

- On balance, the creation of a single regulator is a positive step. However, it is essential that the CQC works appropriately with the new Comprehensive Area Assessment process; it should not lead to the duplication or unnecessary creation of inspection regimes

- The CQC must support councils in achieving their ambitions for local communities. It should not impose its own vision on places. Consideration must also be given to how the three-
way relationship between the CQC, councils and NHS providers will be developed and managed in areas of joint provision.

Part 2 - Regulation of Health and Social Care Workforce

Key Proposals

- Allows for modification of the regulation of the social care workforce in line with the health professions
- Creates the Office of the Health Professions Adjudicator (OHPA) separate from the investigation functions of the statutory professional bodies
- A new responsibility on healthcare organisations and other named bodies to share information about concerns relating to the conuct and performance of healthcare workers and agree the actions needed to protect patients and the public

LGA View

- We believe that any enhancement of professional accountability, whatever the profession, to strengthen protection of individuals is a positive move which will improve service standards
- Effective workforce planning can be reinforced through regulation and the dissemination of good practice and the LGA is supportve of the role of the regulators of professions in setting and maintaining professional standards.

Part 3 – Public Health Protection
Key Proposals

- Amends the Public Health (Control of Disease) Act 1984 to address recent concerns such as contamination by chemicals or radiation and allow the International Health Regulatons 2005 to be implemented
- Allows for powers currently held by councils to, for example require the disinfection or destruction of contaminated articles, to move to Justices of the Peace

LGA View

- The proposed changes to public health legislation are mainly sensible and will consolidate existing legislation into a framewor that will meet new and emerging challenges
- We believe the passing of powers from local authorities to JPs will create an additional layer of bureaucracy that will cause dlays in response to incidents of contamination. It will also cause confusion for businesses as powers under other legislation relating to hygiene and safety will remain with councils
- The additional bureaucracy, as well as extension of powers to chemical and radio logical contamination, will create new financial burdens for councils seeking to protect the public from infection and contamination.

Part 4 - Social Care Finance
Direct payments in lieu of social care services

- Extends the direct payments scheme (a cash payment in lieu of social services) to adults who lack mental capacity to consent to and manage those direct payments

- Payment will be made to someone who can consent and manage the Direct Payment on the individual's behalf.

LGA View

- This is a positive step which extends choice and control over services to those who lack mental capacity

Abolition of maintenance liability of relatives

- Local authorities have discretionary powers under the National Assistance Act 19 48 to ask "liable relatives" (i.e. parents or spouse) to contribute to the cost of care of a relative. This section removes that power.

LGA View

- The LGA supports the removal of this power. This power is variously used by councils throughout the country and is outdated in the context of many modern family relationships. Central government has already provided additional funding within the Access and Systems Capacity Grant to recompense councils for charges that they may have received from liable relatives.

Ordinary residence for certain purposes of National Assistance Act 1948 etc

- Makes provision for "deeming powers" (i.e. decisions about a person's ordinary residence following a hospital stay) and dispute resolution of ordinary residence disputes.

LGA View

- These sections address the important issue of a person's ordinary residence (i.e. the council which will be responsible for their ongoing care) without actually touch ing upon the many factors within a modern and/or chaotic lifestyle which may make the determination of ordinary residence difficult.

- We are disappointed that the Bill does not take the opportunity to offer solutions to some of these disputes rather than merely offering a potentially time consuming dispute resolution process.

Financial assistance to support and encourage social enterprises health and social care provision

- To enable the Secretary of State and other public bodies, including councils, to finance social enterprises delivering health and social care, as well as those

social enterprises providing services that are related to health and social care, provided the social enterprises meet certain qualifying conditions.

LGA View

- This is an important flexibility which will allow councils, who wish to do so, to support social enterprise bodies in their area to provide, or support the provision, of health and social care.

Part 5 - Other matters
Key Proposals

- A non contributory payment for all expectant mothers in the UK to contribute towards the cost of a healthy lifestyle, including diet, during the final weeks of pregnancy, to be administered by Revenue and Customs

- Establishes the National Information Governance Board for Health and Social Care, replacing the Patient Information Advisory group, to ensure the confidentiality and security of records relating to the delivery of services, including those of individual patients

LGA View

- We welcome the increased financial support for expectant mothers, not least in terms of this being helpful in a number of ways including providing for the baby, extending maternity leave or meeting other care needs.

- Given that the NIGB will aim to provide consistent standards for information governance across both health and social care, the LGA welcomes being invited to be one of the key stakeholder organisations represented on the Board.

Further information
For further information on this briefing, please contact Andy Taylor in LGA Public Affairs at andy.taylor@lga.gov.uk or 020 7664 3334.
The full text of the bill can be found here:
http://services.parliament.uk/bills/2007-08/healthandsocialcare.html

NHS Confederation
(This is an article conveying the views of the NHS Confederation)

The Health and Social Care Bill, published on 16th November, will establish a new super-regulator, the Care Quality Commission, which will bring together into one power house the Healthcare Commission and the Commission for Social Care Inspection.

This is a good thing, but MPs should be concerned about how the new regulator will work. NHS trusts cannot focus on tackling healthcare acquired infections, targeting health inequalities, or finding the best and most effective ways of treating patients, if they spend all their time on bureaucratic accounting. This regulator must not increase the bureaucratic burden on NHS organisations. With over 50 organisations already reviewing NHS trusts, it is time trusts had a simpler way of being held to account for their actions based on patient outcomes.

The new Care Quality Commission must therefore approach its task using a risk based model founded on self-assessment. Any requests for extra information from trusts must be backed up by a clear legal remit so that everyone knows where they stand. If power is to move away from the centre, as all three political parties advocate, trust boards must be the drivers for local improvement, subject to the needs of their local population. The regulator must be part of the framework for helping them achieve this. A system which tries to predict every eventuality with the constant potential for intervention is anachronistic, impractical and financially unrealistic.

We could learn from regulators in other sectors and their approaches. For example, the Financial Services Authority and Ofcom tailor their work according to the type and size of organisation they are working with. This is something that we are keen to see brought over into health services.

In seeking to change the burden of proof required in malpractice cases from the criminal standard to the civil standard, the new bill also follows the methods supported by other health regulators. Doctors are understandably concerned about this but we feel that their concerns are overstated. The bill is not aimed at striking more clinicians off – this should remain a final option that will require the strictest burden of proof. It is about reinforcing public confidence so if they make a complaint, they can be sure it will be dealt with – and rectified – properly.

Finally, we must see continuity with what has gone before. The Healthcare Commission's Annual Health Check will be only 4 years old by the time the CQC is established. It can not therefore take a 'year zero' approach and discard what has gone before. NHS trusts are really starting to get to grips with its new self assessment regime and the last health check showed that many trusts had made impressive achievements.

Equally important to all this are patients and the public. Regulation is not a question of branding or a reaction to the latest crisis. For the public, it is about reassuring them that their money is being spent properly. For patients the key is that they are going to be treated safely and with care. It is pointless having a new regulator if the public are suspicious that it will be replaced with a new one sooner rather than later which will introduce yet another regulatory regime that will make comparisons on the progress of its local hospital over a longer period frustrating or worse still meaningless.

The Royal College of Nursing

Health & Social Care Bill
Briefing for Second Reading Debate – Monday 26 November 2007

Background

With a membership of almost 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing

(RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Part 1

CARE QUALITY COMMISSION

Responsibility for the regulation and inspection of Health and Social Care services is currently held by the Healthcare Commission (HCC) and the Commission for Social Care Inspection (CSCI). The Bill proposes combining the regulatory, review and inspection elements of the HCC, CSCI and the Mental Health Act Commission into a newly created body to be called the Care Quality Commission (CQC).

The RCN is concerned that there has been very little detail published about active strategic planning for the merger particularly in relation to how the MHAC will be subsumed in to the CQC. We would not wish to see patient safety compromised by any dilution of the role or effectiveness of the MHAC. The HCC has matured into its role and is now making a significant contribution to the performance management of healthcare organisations and in raising standards of patient care. The RCN does not want to see existing regulation and inspection regimes brought to a standstill whilst the new Commission becomes established. In 2009 Regulation, inspection and enforcement action must continue without interruption in order to safeguard the public and there must be a seamless transition to new methodology and functions in 2010.

We understand that the CQC will run its first year carrying out existing functions of the HCC, CSCI and MHAC which will make more time available for consultation on the various functions for the new commission, and for negotiation on budgets. We would urge the Government to continue to work closely with the Royal Colleges and service user groups to ensure that the functions and methodologies that are adopted in April 2010 are fully consulted upon and absolutely what is required to improve standards and protect the public, and ensure the organisation has enough funding to deliver.

We believe that budgetary and staffing cuts at CSCI are already impinging on its ability to undertake its role effectively. Members have been raising their concerns and questioning the ability of CSCI to safeguard vulnerable people in social care. In a recent snapshot survey of CSCI Trade Union members we found that:

- 77% do not think CSCI is in a position to fulfil its claim “We’re here to make social care better for people”
- 35% know of services in their area that have been registered despite not meeting minimum standards

We know that the Care Quality Commission will be moving towards the Government’s “lighter touch” approach to regulation with decreases in the frequency of inspections and recent changes to the inspection methodology itself. In the aforementioned Trade Unions survey 75% of members reported that they were not confident that the new inspection methodology provides a robust assessment of the risk to service users. We

therefore remain concerned about whether "reducing the burden of regulation" is appropriate when it affects some of the most vulnerable people utilising health and social care services. This is even more critical at a time when the Government is encouraging a wider variety of providers to enter into the market.

In terms of workforce we do have concerns at a time where there is increasing cross-over between health and social care workforce the healthcare workforce will continue to be regulated at a UK level whilst social care will be regulated at a national level.

Chapter 2
REGISTRATION IN RESPECT OF PROVISION OF HEALTH OR SOCIAL CARE

Overall the RCN is supportive of the new system of registration for providers, and in some instances, managers of health and social care, that this Chapter outlines. We support a system of regulation which has standards of care and quality as its utmost priority and look forward to working closely with Government to ensure the regulatory framework will ensure that all service providers and managers are working to meet the highest standards of care and service delivery.

Please find below some more detailed comments on specific clauses in this section:

5 Health or social care

Clause 5 defines "health" or "or social care for the purpose of Part 1 of the Bill as:

(2) "Health Care" includes all forms of health care provided for individuals, whether relating to physical or mental health, and also includes procedures that are similar to forms of medical or surgical care but are not provided in connection with medical conditions"

The RCN is concerned that there is no reference to nursing care in this definition. The current definition of "medical and surgical care" may exclude nursing care and by implication leave this wholly in the domain of social care. We would suggest that the definition in the Bill be amended to read *"medical, nursing or surgical care".* Alternatively we would welcome clarification form the Government that "health care" fully incorporates nursing care.

We also welcome the inclusion of some "cosmetic procedures" under the definition of health care but would welcome more clarity from the Government about which "cosmetic procedures" will be included. In particular we would welcome closer regulation of the non-surgical cosmetic treatment industry which is currently subject to a self-regulatory scheme and we would urge the government to include non-surgical cosmetic treatments such as dermal fillers and botulinum toxin, if they are not already included in this definition.

6 Requirement to register as a service provider

(3) *"In the following provisions of this part, the registration of a person under this Chapter in respect of the carrying on of a regulated activity by that person is referred to as registration "as a service provider" in respect of activity"*

16 Regulation of regulated activities

The RCN believes that it is important that quality and safety are the first of the listed regulatory functions. In a fully competitive market quality standards need to be integrated, across all service providers, by the new regulator.

(4) *Regulations made under this section by virtue of subsection (3)(b) may in particular include provision as to the control and restraint, in appropriate cases, of persons receiving health or social care or other services in connection with the carrying on of a regulated activity.*

The RCN looks forward to seeing the detail of the regulations which will be made under this section. This is an important area which requires clarity in order to protect clients and members. It is essential that all nurses working with vulnerable should be aware of the circumstances in which control and restraint are appropriate. We look forward to working with Government on these regulations to ensure that control and restraint practices are clearly specified for all practitioners.

17 Code of practice relating to health care associated infections

It is important for the regulator to treat Health Care Associated Infection (HCAI) as one of its uppermost priorities. The RCN is pleased that this clause extends the code of practice to all regulated activities, rather than those only carried out by NHS bodies. We are pleased that the Government is extending the Code of Practice on HCAI to all providers of Health & Social Care Services. The RCN has been calling for the Code of Practice to be extended to all Health & Social Care settings as part of its Wipe It Out Campaign for a number of years. We hope that this will help to ensure infection control is a high priority across all settings and should cut down on the risk of infections being transferred from care home settings to NHS settings.

CLAUSES 25-27

These clauses outline the procedures for cancellation, suspension or variation in a service provider's registration should they fail to continue to meet registration standards.

The RCN will be providing more detailed information about the implications of these clauses for committee stage however from our initial understanding we would welcome a further stage to be introduced before cancellation of a service provider's registration which would enable the CQC to intervene and work with the service provider to identify where systems/procedures are failing and can be turned around to meet standards of regulation.

Chapter 3
QUALITY OF HEALTH & SOCIAL CARE

43 Frequency & Period of Review

The RCN has already raised our members concerns with the Minister that changes to existing CSCI inspection methodology are limiting CSCI ability to identify when providers are not meeting the standards set. We are particularly concerned that proposals to reduce the number of inspection for some care homes to a 3 yearly basis, combined with the recent changes to inspection methodology, will be insufficient to protect vulnerable people in care. Currently care homes are subject to unannounced, inspections on a minimum of a yearly basis.

The new system must include a regular review of standards applied and the inspection process used in order to support rather than stifle innovation. The emphasis must be on the provider demonstrating compliance rather than the regulator inspecting for compliance. We would like to see a requirement introduced for providers to report any serious untoward incidents or change in circumstance, for example change of use, registrant or personnel, which may impact on their ability to meet standard. To ensure this is effective there must be additional resource made available for the training and development required to ensure both the assessment managers and the providers have the skills and knowledge to work with this approach.

Chapter 4
FUNCTIONS UNDER MENTAL HEALTH ACT 1983

This section transfers the Mental Health Act commission powers to the Care Quality Commission and in Wales to Welsh Ministers.

Any individual removed from society to a place of treatment is in a vulnerable position and this emphasizes the need for the visiting programme of the MHAC to continue. The Functions of safety and quality are core regulatory functions that should be the sole responsibility of the MHAC with this client group. The RCN has raised concerns about how the role of the MHAC will be encompassed into the CQC as there has been very little strategic detail provided so far. This will be particularly pertinent as the 2007 Mental Health Act will require a higher level of scrutiny to ensure that new measures introduced by the legislation are being implemented appropriately. For example community treatment orders, the use of Section 136, are all areas that will require more regulatory resource and greater scrutiny.

Chapter 6
MISCELLANEOUS AND GENERAL

Inspections

59 Entry and inspection: supplementary
Sub-clause (8) (b) makes no reference to “nursing” records but does refer to “personal or medical” records. We would welcome the “addition of “nursing” records to the clause or

clarification from Government that nursing records will be included in "medical" not "personal records.

60 Power to require documents and information etc

Sub-clause (60) (1) makes no reference to "nursing" records but does refer to "personal or medical" records. We would welcome the "addition of "nursing" records to the clause or clarification from Government that nursing records will be included in "medical" not "personal records.

69 Inquiries

Sub clause 2 outlined below enables the Secretary of State to decide when an inquiry should be held in private:

> *"(2) Before an inquiry is begun, the Secretary of State may give a direction that it be held in private"*

The RCN is concerned that the power to decide whether an inquiry is held in private lies solely with the Secretary of State. This does not encourage a culture of trust in which knowledge that an inquiry will be open and transparent is an integral part of the health service. The RCN would suggest that the exceptional circumstances in which any hearing should be heard in private are set out clearly in primary legislation. We would also want to see that the Secretary of State consults or has approval to hold an inquiry in private from the Health Service Ombudsman and the Care Quality Commission so that the public can be sure that any decision for secrecy does not appear to have a political motive. The rules that currently affect any inquiry allow for parts where information is confidential to an individual to be held in camera but again this should be based against clear criteria set out on the face of the Bill.

Sub-clause 5 outlined below enable the Secretary of State to decide when a report of an inquiry should not be published:

"(5) The report of the person holding the inquiry is to be published, unless the Secretary of State considers that there are exceptional circumstances which make publication inappropriate."

Similarly, the RCN is concerned that this decision should not rest solely with the Secretary of State. The RCN recommends that such circumstances need to be made explicit on the face of the Bill, and that the decision about whether the criteria are met must be with the express approval of the Chair of the Care Quality Commission, reasons for such a decision must be published.

79 Fees

We would like greater clarity about sub-clause 3 outlined below which enables the Commission to set fees in relation to certain registration functions:

> *(3) Provision under subsection (1) may include provision -*

a) *for different fees to be paid in different case*
b) *for different fees to be paid by persons of different descriptions*
c) *for the amount of the fee to be determined by the CQC in accordance with specified factors, and*
d) *for determining the time by which a fee is to be payable*

If these provisions enable the Commission to charge smaller organisation a more reasonable registration rate than larger providers this would be very welcome. However, we would not like to see the provisions utilised to increase charges for larger organisation without a corresponding reduction in costs to smaller organisations.

We would also welcome greater clarity over the criteria to determine different level of fees to be charged. The RCN believes that any proposals for the levels of fees to be charged should subject to further consultation of relevant stakeholders. For clarity it would be helpful for the Government to confirm that it has given consideration to what extent the fees may prevent new entrants from entering the market, the extent to which fees may constrain spending on patient care and how transparent the Care Quality Commission will be required to be in their accountability for spending fees accumulated responsibly.

80 Penalty Notices

The issue of penalty notices raises a number of issues for the RCN and we would never want to see a situation where justice is replaced by economics or where by smaller companies are more negatively impacted upon by a penalty system than larger, multinational companies who may be more readily able to absorb any penalty costs.

In particular we would seek reassurance form the Government that penalty notices will not replace proper enforcement notices or prosecution for those who flaunt the commission's standards. We would also welcome greater clarity on where the income from penalty notices will be re-invested. To ensure parity across all sizes of service providers we would also like consideration to be given to a sliding scale system which would link the penalty charged to the size of the organisation? This would help to address any inequality in a system whereby smaller companies could be hit quite hard for a one off misdemeanor which would not even register on the radar of larger company's.

PART 2
REGULATION OF HEALTH PROFESSIONS AND HEALTH AND SOCIAL CARE WORKFORCE

91 The Office of the Health Professions Adjudicator

The RCN is interested to see proposals for the development of independent adjudication contained in the Bill. We will watch with interest the impact of this on the regulation of doctors and pharmacists as we believe this type of adjudication may soon be extended to other healthcare professions.

92 Fitness to Practice Panels

This clause sets out the procedures, membership and status of fitness to practice panels. The RCN is content with the fundamental role outlined for the fitness to practice panels. However, we are urging Government to ensure that the appointment and selection process for the panels is transparent, equitable and based on the appropriate skills for the job. We would look to Government to ensure that panels are appropriately trained before sitting and that the nurse member on the panel is from the same field of training as the registrant.

98 Procedural Rules

Sub-clauses (2) (e) & (3)
We particularly welcome these clauses which enable the adjudicator to awards costs so that lawyers can seek an order to recoup costs for cases which proceed to a hearing but should not have proceeded.

104 Standard of Proof in Fitness to Practice proceedings

(1) The standard of proof applicable to any proceedings to which this subsection applies is that applicable to civil proceedings.

This section of the Bill lowers the standard of proof in fitness to practice cases from the criminal standard of "beyond reasonable doubt" to the civil standard of the "balance of probabilities". The standard of proof benchmark by which the NMC adjudicator determines has always been the criminal standard of "beyond reasonable doubt" so that NMC panel members must be sure that the facts of the case are proved. If they are not sure a finding of fitness to practice cannot follow.

If the standard of proof is to be lowered to the civil standard NMC panel members would be legally obliged to consider whether it was more "likely than not" that the facts of a case were proved. If this cannot be proved then a finding of unfitness to practice could not follow. Using this approach the respondent registered nurse is diminished and the ease with which a case can be proved by the NMC as prosecutor is correspondingly increased.

It can be argued that it is particularly important to retain the criminal standard in cases of alleged misconduct where many of the facts alleged are, or could be, criminal in nature. Firstly because a situation could arise whereby a registrant is acquitted in a criminal

court using the criminal standard but found guilty using the same facts using the civil standard before the professional conduct tribunal. Secondly, it is important that nurses and employers have confidence in the adjudication process as removal from the register effectively ends a person's career, not just their current employment.

106 Constitution etc. of Council

We are concerned by the proposals that all appointees to the Council for Healthcare Regulatory Excellence will be appointed and will lead to even greater political interference in the workings of the profession. We are particularly concerned about the loss of the Nursing and Midwifery Council seat on the panel which will lead to a further distancing from any notion of "self" regulation.

112 Co-operation between prescribed bodies

(1) The appropriate Minister may by regulations make provision for or in connection with requiring a designated body to co-operate with any other designated body in connection with -

> (a) the sharing of information which relates to the conduct or performance of any health care worker and which may show that that worker is likely to constitute a threat to the health and safety of patients
> (b) the provision of information in response to request for information from any other designated body about the conduct or performance of any health care worker

The RCN is concerned that the detail of this clause remains to be worked through by the Secretary of State, with very little detail provided on the face of the Bill. Is there evidence to support the need for statutory powers in ensuring co-operation between prescribed bodies?

Even if powers were only to be extended to the NHS with social care employers required to report nurses to the NMC the RCN would continue to have strong objections. There has been no evidence to support the need for this new obligation and employers are already experienced in sharing such information on a voluntary basis.

The NMC routinely drops the majority of referrals because there is "no case to answer" therefore there is little evidence of under-reporting and no indication that there is a gap in reporting by a nurse who then does become a threat. The cost for the RCN and the cost for nurses would be exorbitant if every employer is required under pain of criminal conviction to refer. It is clear that the cost of investigation will not be borne by the Secretary of State but will fall directly to nurses who will have to pay higher costs to NMC through registration fees and also to the RCN for additional cost of representation for the new cases.

There is a serious danger that this obligation will lead to a drop in trust between nurses and employers and employers and Government. Likewise it could reduce the incentive for nurses to report errors or near misses if the consequence is an automatic referral to the NMC?

Furthermore, health care staff are regulated by different agencies and to different standards. For example a nurse is regulated by the NMC and will be directly affected by the Safeguarding Vulnerable Groups Act 2006 when it comes into force in 2008. Whilst an employer faces a £5000 fine for any failure to report directly to the Secretary of State any harm, or risk of harm, by a care worker. We fear that this is another layer of regulation that demonstrates a low risk of trust in care workers and adds another layer of regulatory to checks to an already overlapping and inconsistent regulatory system. The RCN would urge the Government to look closely at the intertwining regulatory systems already in operation and use Health and Social Care Bill as an opportunity to encourage greater consistency across regulatory systems.

PART 3

PUBLIC HEALTH PROTECTION

45A Infection or Contamination

Updates existing legislation regarding spread of infection or contamination in emergency circumstances to cover modern aspects of public health protection including contamination by radiation or chemicals. The RCN welcomes Government measures to update and modernise infection and contamination procedures to meet modern day risks. We will endeavor to provide more detailed briefing on this part of the Bill ahead of committee stage.

PART 4

HEALTH IN PREGNANCY GRANT

The RCN worked closely with Government in developing the Health in Pregnancy Grant. We are supportive of the Government's plans to take active steps to send out a positive message to women about the importance of keeping good health during pregnancy. We are pleased that the proposals in the Bill ensure that the grant will be non-means tested and available to all pregnant women. We are particularly supportive of measures in the Bill to ensure that expectant mothers have improved access to advice on living a healthy lifestyle from healthcare professionals, as their continued health during pregnancy is important for themselves, their baby and their family. Informing women about the health in pregnancy grant will give health care professionals an ideal opportunity to inform women about other benefits that may be available to them such as the sure start maternity grant.

As the health in pregnancy grant will be working throughout the UK we would welcome consideration when drafting the regulations to ensure that the definition of “health professional” in the secondary legislation will be wide enough to take into account the differences in the delivery of health and maternity services between the four countries.

Northern Ireland

The RCN is concerned that there may be a drafting anomaly in this section. According to the Bill and corresponding explanatory notes the Health in Pregnancy Grant does not apply to Northern Ireland. However, clauses 124 and 157 (2) go on to confirm that the Grant will apply to Northern Ireland, albeit within the framework of an amendment to a different piece of legislation. We would welcome clarification on how this will move forward and if the Bill will be required to be amended to reflect that the Grant will also apply in Northern Ireland.

PART 5
MISCELLANEOUS
Amendments Relating to National Health Service

131 Indemnity schemes in connection with provision of health services

This clause extends indemnity schemes to non-NHS bodies that provide services or secure the provision of services.

The RCN welcomes the extension of the Clinical Negligence Scheme for Trusts (CNST) to all independent providers who deliver the types of care currently covered by the scheme. The new arrangements will support the increasing diversity of provision of health care and will provide a consistent and more effective approach to the handling of clinical negligence claims. In turn this will give reassurance to both patients and health care staff that there will be no inequalities in how unfortunate adverse clinical incidents will be handled, irrespective of the nature of the provider. It will also hopefully lead to the widespread implementation of consistent and robust risk management procedures, despite the variety of providers. We would welcome the extension of the CNST to providers of primary care services generally, as the arguments in favour of such a scheme apply to providers of both secondary and primary care. Although membership of the CNST will apparently remain voluntary, we would expect commissioners of NHS care to be robust in ensuring that any insurance alternative offers the same levels of provision as the CNST.

Finally, we expect government reassurance that any extension of the CNST will be accompanied by the publication of guidance on the 'NHS Indemnity' (HSG(96)48), particularly in relation to the requirement that the provider takes full responsibility for managing and, where appropriate, settling all clinical negligence claims without the provider seeking to recover any proportion of the costs from health care professionals or others covered by the NHS indemnity, or from any private indemnities which these individuals may have.

132 Weighing and Measuring of Children: England

The RCN supports proposals that help school nurses share information with parents on the well being of their children. Any attempt to increase appropriate dialogue between parents and school nurses is a positive step forward. Primary Care Trusts and the Government need to work together to ensure that every child has access to a school nurse by making the adequate resources available. The RCN is concerned that progress to achieve the Government's target of one qualified school nurse in every secondary school and its cluster primary schools is slow, with evidence indicating that many school nursing teams have been adversely affected by the impact of NHS deficits. The National Audit Office, Health Care Commission and Audit Commission 2006 report 'Tackling Child Obesity – First Steps' indicated that Head Teachers reported their ability to address health issues such as obesity was seriously inhibited by the lack of access to a health professional within schools and other educational settings.

134 Direct Payments

Makes provision for a system of direct payments to purchase social care services directly from a Local Authority to be extended to individuals under the mental capacity act. Where individuals are deemed to lack the capacity to consent to direct payments a "suitable person" can be nominated to receive the payment on their behalf.

The RCN welcomes the extension of direct payments to individuals under the Mental Capacity Act however we would like to see clear safeguards put in place to ensure that these vulnerable individuals cannot be exploited. It is imperative that clear guidelines are issued to ensure that any nominated "suitable person" will be acting in the best interest of the individual lacking capacity to commit to direct payments.

137 Power of Secretary of State to give financial assistance

The RCN is supportive of the principle that the Secretary of State should intervene financially to ensure continuity of services where providers exit the market. However, we would welcome much greater detail about the failure regime for Foundation Trusts. It would be helpful to have clear criteria for circumstances where the intervention of the Secretary of State would be desirable. For example financial assistance to build capacity, develop staff for a particular innovation in service delivering, or in order to improve a facility where it is not meeting the standards required by the Care Quality Commission.

The RCN would welcome confirmation that the Government are content that the kind of assistance they have outlined in the Bill will meet EU legislation requirements around what is and what is not 'state aid'.

If you require any additional information ahead of second reading please do not hesitate to contact the RCN parliamentary office on 020 7647 3628.

Royal College of Nursing
November 2007

Royal Pharmaceutical Society of Great Britain

Royal Pharmaceutical Society of Great Britain

Briefing Note for the Second Reading of the Health and Social Care Bill

The main areas on which the Royal Pharmaceutical Society of Great Britain (RPSGB) would wish to comment are:

The Bill

The Health and Social Care Bill is a wide-ranging piece of legislation that seeks to accomplish many outcomes. A major facilitator of these outcomes will be secondary legislation, on which stakeholder organisations - such as the RPSGB - are engaging with

the Department of Health to ensure effective outcomes. A large proportion of the content that could be within the Bill is expected to appear within subsequent secondary legislation which is not ready to be shown to stakeholders, who can only reserve their position until the full detail is made available.

RPSGB understands the need for this legislation to have the inbuilt flexibility only made possible by the use of secondary legislation. We suggest the Government should also accept that it is asking healthcare bodies – in particular the RPSGB – to accept unseen legislation that could have a pivotal effect on the role of pharmacy in the UK and a commensurate impact on the public.

Care Quality Commission

Chapter 3 of Part 1 of the Bill in its current form suggests that the Care Quality Commission (CQC) will have the power to: *'carry out periodic reviews of care provided by or under arrangements made with Primary Care Trusts* (PCTs*). It also requires the Commission to review health care provided by PCTs…'*[135]

The RPSGB is unclear as to the extent of the nature of those reviews and how they will relate to inspections that are currently conducted by those bodies that will form the CQC and also the inspections of registered retail pharmacies conducted by the RPSGB. The lack of a clear definition of what is a: *'regulated activity'* in relation to the CQC results in current confusion around what aspects of health care it will regulate.

It is clear that the nature of inspection will change as pharmacy takes on a more clinical role, but greater clarity is required for the profession to be fully engaged in the consultation process.

Duplication and clarity of roles

The Bill portrays a vision of the roles of health care regulators developing, expanding and modernising to maintain utmost relevance to their role. Whilst it is appreciated that the Bill attempts to cover a dynamic and fluid situation, it fails to demonstrate a clear image of what the Government anticipates in relation to a new regulatory environment. Health care practitioners suspect a regime where they are required to register with more than one regulator and could be subject to dual inspections. This together with the likelihood of differing standards being utilised by different regulators adds to the confusion about the boundaries of the remit and scope of the CQC.

Global Sum

The Bill devolves budget holding of the Global Sum – the sum currently paid by the Department of Health for the provision of essential services in England, and similar services in Scotland and Wales. It will be devolved from the Department of Health to Primary Care Trusts.

The RPSGB is pleased to see an initiative that provides funding to bodies that are able to respond to the specific health care needs at a local level. Any such change is likely to result in delay and initial operational problems before a new system is at full operating efficiency. The RPSGB is most keen to see a smooth transition from centrally to locally

[135] Explanatory Notes to Health and Social Care Bill, section 11

held budgets without any delay to the process, which may have an effect on the financial standing of some pharmacies.

Transfer of Functions
The Bill refers to transferring: "all of the RPSGB's functions" to the General Pharmaceutical Council. The RPSGB believes this is not what is intended by the Government and expects further clarification on this point.

Standard of Proof
The Bill makes consistent the standard of proof in fitness to practice proceedings across all regulatory bodies, using the civil standard of proof. This is welcomed by RPSGB.

Extension of powers under s60 of the Health Act 1999
The RPSGB welcomes the extension of powers under s60 of the Health Act 1999 in relation to provisions affecting the registration and regulation of the use of pharmacy premises and considers these powers essential in ensuring adequate regulation in the future.

Summary
The Health and Social Care Bill is an enabling Bill that has an inbuilt element of future-proofing via its reliance upon secondary legislation. The Bill that has commenced its passage through Parliament appears to be very much a case of 'work in progress' rather than a vision of healthcare regulation fit for the future.

UNISON

Briefing on Health and Social Care Bill

House of Commons Second Reading – 26th November 2007

Introduction

UNISON is the major union in the health service and social care. We represent more than 450,000 health care employees and 300,000 social care employees employed in the NHS and local government, and by private contractors, the voluntary sector and general practitioners. We also represent employees across the range of disciplines in both the Commission for Social Care Inspection (CSCI) and Healthcare Commission.

UNISON supports the Government's emphasis in the Health and Social Care Bill on the importance of public protection. Our key concerns in both the aspects of the bill around the regulation of health and social care services, and the regulation of health and social care professionals, centre on areas in which we believe that provisions will not maximise the ability of staff to ensure public protection.

UNISON welcomes many of the public health elements to the Bill and would wish to work with the Government to ensure safe and effective implementation. We will provide more detailed information in our committee stage briefing.

Key concerns

PART 1 – The Care Quality Commission

The regulation of health care and social care in England is currently carried out by the Healthcare Commission and the CSCI. The Bill proposes the establishment of a new body called the Care Quality Commission (CQC), responsible for the registration, review and inspection of certain health and social care services in England.

The Government has said that the principles of inspection will be 'proportionate' and 'risk-based' with a view to lightening the burden of regulation for health and social care providers. For example, in place of the annual reviews currently conducted by the Healthcare Commission and the CSCI, the new Commission will only carry out periodic reviews of PCTs, NHS providers and local authorities. The move to less frequent inspection of care providers looks set to continue – providers previously required to be inspected twice a year may only now be inspected once every three years.

UNISON is concerned that continuing moves towards light touch regulation could have massive implications for public and staff safety. We are concerned that at a time when the Government is encouraging more providers into the market, this is being met by less regulation.

In particular, we have concerns that the new CQC will not be required to take on some of the important functions carried out by the previous inspection bodies. For example, the new regulator will not be responsible for responding to individual complaints about service providers. As those who fund their own care, which makes up 35% of total numbers of recipients of care services, do not have access to the Local Government Ombudsman, this means that a significant number have no independent redress against deficiencies in the quality of care they receive.

As the Government has already announced that the new regulator will have to operate with a budget that is 40% less than what the previous regulators had, UNISON is concerned that the inspection system is being driven by budget imperatives, rather than what is best for users of health and social care services.

We would also like to see a specific focus and powers for the new regulator to enforce the requirements on providers set by the General Social Care Council (GSCC) in relation to the social care workforce. At present the GSCC enforces the Code of Practice for social care *employees* while formally it falls to the Commission for Social Care Inspection to enforce the Code of Practice for social care *employers.* However, it is generally agreed that there is no real enforcement of this Code.

When compulsory registration of the next groups in the social care workforce commences next year, it is envisaged that enforcement of the registration requirement for all staff working in regulated social care settings, will rest with the CSCI and subsequently with the CQC. This differs from the current position, where the enforcement mechanism is through criminal sanctions against anyone found to be presenting themselves as a social worker who is not registered.

We have grave concerns that the policy of workforce registration together with training and learning requirements, which UNISON has supported, will be fatally undermined if there is insufficient enforcement, and providers slip through the net creating a two-tier system. This is particularly important as eventually compulsory registration will be extended to 800,000 staff. We therefore think it is imperative that the Bill and subsequent regulations give specific enforcement powers and resources to CQC to give the public confidence that *all* care staff will be professionally registered and competent to care for the most vulnerable in our society

PART 2 – Regulation of health professions and the Health and Social Care Workforce

The Office of the Health Professions Adjudicator

Provision is made in the Bill for the creation of a new body to be called the Office of the Health Professions Adjudicator ('the OHPA'). The OHPA is intended to provide legislative underpinning for the separation of adjudication of fitness to practise cases from their investigation and prosecution. Whilst these proposals will initially affect the General Medical Council and General Optical Council, the White Paper *'Trust, Assurance and Safety'* has indicated that this separation is the direction of travel for all regulators. In principle UNISON would support this direction of travel, although we would wish to be closely engaged with the monitoring and reviewing of the system.

However, the fitness to practise process is currently funded by the registrants of the individual registration bodies and is seen as part of the process of professional regulation by the staff. The proposals in the Bill will in effect create an independent tribunal system which will not guarantee that a professional's case will be heard by one of their own. We would argue that one of the panel members should be from the relevant register to ensure that judgements are fair and in line with normal professional practice.

In addition the cost of the system could be in excess of the current system and will reduce the ability of the registration bodies to perform their other functions as registrar and champions of professional development. If this separation of functions is for public protection, it is legitimate to ask whether it should be financed by central funds and not by the registrants.

Amendments of Part 3 of Health Act

Extension of powers under section 60 of Health Act 1999 (clause 103 and schedule 8)

Under the current Health Act 1999, a section 60 order cannot require a majority of the members of a regulatory body to be lay members. The current Bill removes this restriction. UNISON continues to have concerns over the make-up of the boards of the health regulators. The NHS Appointments Commission has so far failed to appoint board members who allow representation across the ethnic, social and gender divides. It is absolutely key that the new councils are able to engage with the registrants of the professions which they regulate, and reflect society.

Currently none of the existing regulatory bodies are compliant with the equalities legislation. We would wish to see that the Bill, as a minimum, requires regulators to meet the obligation under these Acts. Failure to achieve this could undermine the confidence that both registrants and the public have on their ability to function fully.

Standard of proof in fitness to practise proceedings (clause 104)

This clause amends the Health Act 1999 to impose a requirement for all regulatory bodies and the new OHPA to use the civil standard of proof (the balance of probabilities) rather than the higher, criminal standard of proof (beyond reasonable doubt) in fitness to practise proceedings.

UNISON has particular concerns in relation to this part of the Bill, given the huge impact that the decisions of fitness to practise proceedings have on the livelihoods of healthcare professionals. Removal from a register is communicated to all registers, and effectively ends a person's career. It is therefore vital that confidence exists in the decision being made by the regulators. We also have concerns that certain minority groups will be affected negatively by this changing standard**.** As none of the regulators comply with the Race Relations Act, they do not publish information on either the ethnicity of their registers or decisions taken. However anecdotal evidence seems to show a higher proportion of black and minority ethnic registrants in some professions being subject to fitness to practise in comparison with other groups. Finally, if some of the less severe cases are judged by the civil standard of proof, this may create a bottle-neck in the system, leading to a delay in the consideration of the more severe cases of professional misconduct.

Council for Healthcare Regulatory Excellence (clauses 105 – 109, plus schedule 10)

The Bill changes the name of the Council for Regulation of Health Professionals (CRHP) to the Council for Healthcare Regulatory Excellence (CHRE) and makes provisions regarding the constitution of the CHRE. Currently the presidents of the regulators sit on this body, whereas the proposals in the Bill reduce the present council from nineteen to nine members. Again, UNISON has concerns over the representation and transparency that this new council will provide for healthcare professionals. We believe that every effort should be made to ensure that black and ethnic minorities are appointed to the board. It is essential that the new CHRE reflects society and is not made up of full time committee members.

We would ask that the NHS Appointments Commission plays particular attention to the short listing of board members – we are aware of one individual who sits in different capacities on seven different regulatory bodies. Public protection should be seen as a civil duty similar to that of jury service and we should seek to ensure that we not only have the right people in place with the correct skills but that these individuals bring life skills and an interest in public protection.

Conduct and performance of medical practitioners and other health care workers (clause 110)

The Bill provides the legislative underpinning for oversight of local elements of revalidation through the establishment of the role of the "responsible officer". The role of the responsible officer includes a duty to cooperate with the GMC in connection with its responsibilities for medical revalidation. It is likely that this system will eventually be extended to the other regulators, and UNISON has concerns that the direction of travel of revalidation is to move towards a licensing as opposed to a regulatory system.

Licensing would change the relationship between the registrar and the registrants and would result in a system with less emphasis on continued professional development and more on competency tests. It also makes the merger of registration bodies easier since it assumes that once a license has been issued the involvement of the registration body in monitoring the professional is less than

as of now. The emphasis of the registration body would move from professional development to a competency test at entry and at the time of possible removal from the register.

We would wish to be actively involved in any discussions surrounding revalidation as proposals for doctors may not readily translate into practical measures for other staff groups.

Regulation of social care workforce (clauses 114 – 115)

This section of the Bill enables the Secretary of State to make regulations modifying the regulation of social care workers, including their registration, and education and training. Given that UNISON represents 300,000 of members across social care, we are particularly interested in this aspect of the Bill, and the intentions behind it. UNISON believes that if we are to achieve full public protection, any moves to widen the scope of regulation need to ensure that the system is effective and simple for staff to navigate, and is one that they have confidence in and crucially, can afford.

The cost of registration for care assistants is a major issue in view of the low pay levels which prevail for this workforce and the high incidence of part-time and casual contracts. The current figure of £20 pa has to be seen alongside other charges such as the Vetting and Barring scheme costs and Criminal Record Bureau checks. We believe there should be a grandparenting process that would allow care staff to gain the required qualification over a period of three years. The six years currently proposed by the General Social Care Council represents a missed opportunity to drive up qualification levels in the sector, because of the level of staff turnover that will occur over such a long period.

PART 5 - Miscellaneous

Amendments relating to National Health Service

Inquiries (clause 69)

It is difficult to identify how public protection can be secured if the Secretary of State can instigate inquiries to be undertaken in private. UNISON has concerns regarding this clause and will seek to provide more information in a committee stage briefing.

Co-operation between prescribed bodies (clause 112)

UNISON wishes to give further consideration to this clause. We have concerns that it may not comply with the Human Rights Act and wish to review it in light of advice and the consultation which is currently taking place on Safeguarding Vulnerable Groups. The Bill lacks detailed information on this clause.

Indemnity schemes in connection with provision of health services (clause 131)

This clause sets out to amend the primary legislation that allows the Secretary of State for Health to create schemes for meeting losses and liabilities amongst providers of NHS healthcare. Whilst the focus of the clause is to bring the private and independent sector into the NHS scheme, UNISON is concerned that it does nothing from preventing this sector from pushing the burden onto individual employees by making indemnity insurance a requirement of their employment. A move to apply liability onto an individual would not be supported by staff and the unions.

Conclusion

We are concerned about the planning for the merger to create the Care Quality Commission and we would not want to see a reduction in standards of inspection because of budget cuts and staff reductions. The definition of healthcare which will covered by the CQC appears to omit nursing care and we believe this section requires rewording since the bulk of registered nursing homes provide that level of care.

The changes in the regulation of health professionals and the reduction in the standard of proof in fitness to practise cases is of concern because of the possibility of increased fees to registrants caused by the cost of the new structures and the possibility of licensing not registration.

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If you require further information or would like to meet to discuss any of these issues, please contact:

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