Title:
Regulation of healthcare professionals and social care professionals in England
IA No: LAWCOM0032

Lead department or agency:
Law Commission; Scottish Law Commission; Northern Ireland Law Commission

Other departments or agencies:
Department of Health; Scottish Government; Department of Health, Social Services and Public Safety for Northern Ireland

Impact Assessment (IA)

Date: 02/04/2014

Stage: Final

Source of intervention: Domestic

Type of measure: Primary legislation

Contact for enquiries:
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Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£72.95m	£0	£0	No	N/A

What is the problem under consideration? Why is government intervention necessary?

There are 32 regulated health and social care professions, within the scope of this project, with a total membership of just over 1.44 million. The professions are regulated by nine regulatory bodies, each of which is subject to its own individual piece of governing legislation. The complex legislative landscape that has evolved over 150 years is inconsistent, inflexible and expensive to maintain. A streamlined and modernised system would be responsive to the needs of modern regulation, proportionate to the risks involved and clear about the purpose of ensuring public protection. Accordingly, it would be beneficial to reform the legal framework and this will require primary legislation.

What are the policy objectives and the intended effects?

The policy objectives are: (1) the simplification of the legal framework to allow the law to be easier to understand for the public and professionals; (2) consistency of powers between the regulatory bodies, which would allow the public and professionals to be clearer about what to expect from the regulatory scheme; (3) increased flexibility and autonomy for the regulators to keep pace with changes in health and social care; (4) clear accountability mechanisms for regulation; and (5) enabling cost efficiencies.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0: Do nothing

Option 1: Simplification and reform of the health and social care professional regulation legislative framework (the preferred option). In general terms, this option involves consolidating existing legal provisions and establishing a more efficient and effective legal structure.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes/No	**< 20** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description:

Simplification and moderate reform of the health and social care professional regulation legislative framework

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**
2012/13	2013	**10**			**£72.95**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.13		0.11	**1.05**
High	0.41	1	0.11	**1.33**
Best Estimate	0.33		0.11	**1.25**

Description and scale of key monetised costs by 'main affected groups'

Transitional Costs: Training fitness to practise panels – best estimate £330,000 [Regulators]; Creating new rules and regulations [Regulators];
On-going costs: Additional staffing requirements of the Professional Standards Authority – best estimate £111,178 per annum; Creating new rules [Regulators].

Other key non-monetised costs by 'main affected groups'

None identified

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0.0		£3.77	**£31.4**
High	0.0		£17.47	**£145.3**
Best Estimate	0.0		£8.92	**£74.2**

Description and scale of key monetised benefits by 'main affected groups'

No transitional benefits indicated.
On-going benefits: Annual efficiency savings for the regulators – best estimate £8,498,385; Reduced Department of Health expenditure on legal support – best estimate £421,868 per annum

Other key non-monetised benefits by 'main affected groups'

Reduced risk to the public; Increased public trust and confidence; Increased flexibility and the capacity to quickly respond to environmental and organisational change; Improved information sharing.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Assumptions: Powers will not be enacted by a regulator unless there is a net benefit which may accrue to a stakeholder that is not bearing the direct cost.
Risks: Variation in regulator size means that there is considerable divergence in the distribution of total costs and benefits amongst regulators; there is the medium risk of the over-estimation of benefits and costs as some of the recommendations may be implemented before the entry into force of the draft Bill.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes/No	IN/OUT/Zero net cost

EVIDENCE BASE

Background to the problem

The professional regulatory scheme for UK health and social care professionals consists of a number of different statutory regulators:

1. General Chiropractic Council;
2. General Dental Council;
3. General Medical Council;
4. General Osteopathic Council;
5. General Optical Council;
6. General Pharmaceutical Council;;
7. Health and Care Professions Council;
8. Nursing and Midwifery Council; and
9. Pharmaceutical Society of Northern Ireland.

However, the Pharmaceutical Society of Northern Ireland will not be incorporated into the new legal framework as its dual representational and regulation roles are not sufficiently aligned to those of the other regulators at present. For the purposes of this impact assessment, subsequent references to the regulators do not include the Society. The project also covers the Professional Standards Authority which oversees the regulators. It was previously known as the Council for Healthcare Regulatory Excellence.

The health and social care regulators maintain professional registers, set standards for education and practice, and ensure that professionals are fit to practise. Collectively, the regulators are responsible for the standards of practice of about 1.44 million professionals (see Table 1 below). There is considerable variation in the number of registrants from the highest value of just under 674,000 at the Nursing and Midwifery Council to approximately 2,900 practitioners registered with the General Chiropractic Council.

Statutory regulation of health and social care professionals can be traced back over the last 150 years, to the establishment of the General Medical Council in 1858. Each regulator, and the Professional Standards Authority, is governed by a separate piece of legislation. These have all been amended extensively by Orders made under the Health Act 1999 and a range of Acts of Parliament over the last 10 years. We have estimated that there are close to 200 pieces of secondary legislation which specifically address the regulators. The current legal framework is highly complex, inflexible, inconsistent and expensive to maintain. Accordingly, there is need for reform, which is recognised by the regulatory bodies as well as the Department of Health. For these reasons, the Department of Health suggested a project to review the legal framework for health and social care professional regulation. The purpose of the recommendations in the final report is to address these problems by establishing a simple, consistent, flexible, accountable and efficient modern legal framework (see *policy objectives* below).

The problem under consideration

Complexity of the legal framework

The piecemeal development of primary and secondary legislation in the area of health and social care regulation over 150 years has resulted in a complex legal framework. Regulators operate within a wide variety of legal frameworks which have been agreed and amended by Parliament in different ways and at different times. A complex legislative landscape has led to a wide range of idiosyncrasies and inconsistency in the powers, duties and responsibilities of each of the regulators.

Inconsistencies in the legal framework

As a consequence of the complex legal framework, inconsistencies have developed, many of which cause confusion to the public and registrants and result in different levels of public protection. For example, in fitness to practise proceedings, some regulators have powers to establish systems of case

management, while others do not. Some are able to screen allegations of impaired fitness to practise, while others must refer all complaints to an investigation committee. The powers to take action against practitioners whose fitness to practise is impaired also vary.

Inflexibilities in the legal framework

The regulators' legislation is difficult to alter and keep updated. Consequently, the legal frameworks can often be out of step with regulatory demands, and not provide the highest possible levels of public protection. The main legislative vehicle for altering the governing legislation is an Order made under section 60 of the Health Act 1999, which can take two years to be implemented once the proposal has been agreed.

Costs of the legal framework

The current legal framework gives rise to a significant cost burden on the regulators and the Government. The total annual expenditure of the regulatory bodies in 2012/13 was just over £230 million. The operating costs of the regulators are met through fees paid by registrants themselves. Since fees are partially tax deductible there are commensurate cost pressures on both the Government and the tax payer.

The regulators have powers to make rules and regulations concerning their operating procedures but the requirement of Privy Council approval imposes burdens on the Department of Health. In practice, the Privy Council defers to the Department's policy officials and legal group when the Council is required to act. Constraints on Government resources mean that only the most pressing matters are taken forward, thereby restricting the regulators' ability to instigate reforms and modernise their legal frameworks. By creating a flexible legal framework, there is an opportunity to significantly reduce departmental expenditure on health and social care regulation.

Rationale for intervention

The conventional economic approach to Government intervention to resolve a problem, is based on efficiency or equity arguments. The Government may consider intervening if there are strong enough failures in the way markets operate or if there are strong enough failures in existing interventions (for example, waste generated by misdirected rules). The proposed intervention should avoid creating a further set of disproportionate costs and distortions. The Law Commissions' objectives in seeking to reform the legislative framework are to address the problems identified above in order to create a modern and simplified system of regulation that will protect the public and maintain confidence in the professions.

The regulators' activities concern matters of overwhelming public interest, and can have significant resource implications for both themselves and third parties. A coherent legal framework and Government oversight is, therefore, essential. The regulators are bound to carry out their functions within the applicable legal framework, and so it is crucial that the legislation provides an effective legislative structure. However, the complexity, inflexibility and cost of the current legal framework have fostered inefficiencies which pose a threat to the regulators' ability to protect the public. Setting out the legal powers and duties of the regulators in a manner which is accessible to the public and registrants will promote transparency and understanding of regulation. It will also provide the regulators with tools to develop systems of regulation that can react to changing regulatory demands, and that can perform more efficiently. The combined effect of all of these outcomes will be a system that is well equipped to protect the public, and maintain public confidence. The clarification of the regulators' legal powers and duties required to achieve these outcomes can only be achieved through reform of the law.

Policy objectives

There are five policy objectives.

Simplification

The purpose of reform would be to develop a legal structure that replaces the current position of dense and complicated law with a clearer and more cohesive framework. This would enable the law to be more easily understood by the public and registrants, thereby promoting confidence in the regulation of health

and social care professionals. Furthermore, a simplified legal framework would make the law easier to use for the regulators by clarifying their legal powers and duties.

Consistency of powers

A key objective of reform is to establish consistency in the fundamental powers and functions of the regulators in key areas, by replacing the separate pieces of legislation with a single, consolidated statute. This would have benefits for service users and registrants as they would be clearer about what to expect from the regulators. For example, the differing fitness to practise procedures and sanctioning powers available to regulators can cause confusion when members of more than one profession are investigated in relation to the same incident. The regulators would feel benefits themselves by being able to make decisions in parity with other regulators and thereby develop shared learning points through which performance could be improved.

Flexibility

Reform of the legal structure is required to give the regulators greater flexibility. Under present arrangements, the regulators are straight-jacketed in their ability to provide regulatory solutions. A legal framework that enables regulators to create their own rules using streamlined processes, such as with less input from the Department of Health, should help produce a system which is able to react to changing regulatory demands and developments.

Accountability

The need for proper modes of accountability is an important factor behind our proposals. Currently the role of the Privy Council is illusionary and in reality the Government holds the regulators to account. Our scheme aims to clarify this division of responsibilities. The regulators would also be subject to oversight from the Professional Standards Authority and from the public through consultation requirements.

Cost efficiencies

An express aim of this project is to help achieve cost efficiencies in professional regulation. Under present arrangements, resources are used inefficiently by requiring the Department of Health to oversee changes to the regulators' rules and regulations. The costs associated with this include the resources required to amend and negotiate the content of draft rules proposed by the regulators, the preparation of legal advice, and efficiency costs in terms of delays. A feature of our proposals would be that the Department of Health would no longer be required to have any input into the regulators' own rule-making processes, and it is anticipated that there are significant overall efficiencies to be had by moving the responsibility for changes from the Department of Health on to the regulators themselves. This would include efficiencies associated with having fewer layers in the change process. The public would benefit from a system which requires reduced expenditure from central Government. Furthermore, the public and registrants would benefit since the regulators would be able to introduce a more streamlined and efficient service.

Scale and Scope

The following sets out the scale and scope, mainly in terms of cost, of the health and social care professional regulatory sector that is within the remit of our project. In the main, we rely on figures from the regulators' publicly available information. This is primarily found in their recent annual reports and accounts. There is, however, considerable variation in the reports in terms of the areas covered and the level of detail. It is, therefore, important to note that it is not always possible to compare like with like. We recognise the data limitations of identifying an average given the wide variation in values and attempt to mitigate this to some extent through the use of a range in the subsequent cost benefit analysis.

Professional Standards Authority

The Professional Standards Authority oversees the regulatory bodies. A feature of the reforms is that they will reinforce the Professional Standards Authority's oversight role, and confer a small number of additional powers and duties. The Professional Standards Authority total expenditure for 2012/13 was £3,195,000. Its standards and regulation work accounted for £2,758,000 of that total.

Number of regulators/registrants and annual expenditure

There are approximately 1.44 million professionals registered with the health and social care regulators (excluding the Pharmaceutical Society of Northern Ireland). Those regulators regulate 31 different health and social care professions.

The number of registrants is dependant on the number and size of professions within the remit of each regulator. For instance, the General Medical Council regulates a single, relatively large profession (medical doctors) whilst the Health and Care Professions Council currently regulates 16 different professions of variable sizes. Other regulators might regulate professions associated with its core profession. For instance, in addition to dentists, the General Dental Council regulates dental hygienists, dental therapists, clinical dental technicians, orthodontic therapists, dental nurses and dental technicians. The figures from the General Pharmaceutical Council and the General Optical Council include registered premises and businesses respectively. Table 1 sets out the registrant numbers alongside annual expenditure (total and average).

Table 1: Regulatory bodies, registrants and expenditure (Total and average)

Regulatory body	Period	Number of Registrants	Total expenditure (£)	Per registrant Expenditure(£)
Nursing and Midwifery Council	2012/13	673,567	£63,266,000	£94
Health and Care Professions Council	2012/13	310,942	£20,049,000	£65
General Medical Council	2012	245,903	£88,422,000	£360
General Dental Council	2012	101,594	£30,624,000	£301
General Pharmaceutical Council	2012/13	83,417	£16,278,000	£195
General Optical Council	2012/13	21,448	£6,797,068	£317
General Osteopathic Council	2012/13	4,688	£2,684,101	£573
General Chiropractic Council	2013	2,892*	£2,362,650^	£817
Total		**1,444,451**	**£230,482,819**	

Source: Nursing and Midwifery Council, *Annual Report and Accounts 2012 – 2013* (2013); General Pharmaceutical Council, *Annual Report and Accounts 2012/13* (2013); General Dental Council, *Annual Report and Accounts 2012* (2013); General Medical Council, *The state of medical education and practice in the UK 2012* (2012); Health and Care Professions Council, *Annual Report and Accounts 2012 – 13* (2013); General Optical Council, *Annual Report and Accounts 2012 – 2013* (2013); General Osteopathic Council, *Annual Report and Accounts 2012 – 2013 (*2013); General Chiropractic Council, *Council Meeting Reports, 8th August 2013*. *estimated 3% increase on 2012 population end of year figure [2808] to give 2013 end of year. ^end of 2013 estimate.

The amount spent by the regulators is unevenly distributed, with the General Medical Council spending significantly more than any other regulator. The data suggests that even where a regulator has a large number of registrants, this does not mean that more money is necessarily spent. In fact, the two largest regulators in terms of registrant numbers, the Nursing and Midwifery Council and the Health and Care Professions Council, have the lowest average spend per registrant. The General Osteopathic Council and the General Chiropractic Council have the largest average spend. A possible conclusion from these figures is that the larger regulators benefit from economies of scale.[1] However, these figures are the total

[1] Economies of scale refer to the reduction in average cost as a result of increased size of an operating unit.

expenditure by each regulator, and so may take into account a wide variety of costs. The figures in respect of specific activities and functions may provide a more reliable basis for comparison.

The regulators tend to report their costs according to their main areas of activity, which reflect some of the key areas covered by the reform proposals:

- Governance;
- Registration;
- Education and standard setting; and
- Fitness to practice.

Governance

In general terms, governance costs relate to the costs of running a General Council and committees. This can include the expenses of the members of the General Council and committees, as well as administrative costs. The governance costs associated with each Council depends on the size of the Council as well as the different governance structures that exist at each regulator. Table 2 below sets out the governance costs of the regulators.

Table 2: The governance costs of selected regulators

Regulator	**Period**	**Average governance cost per registrant (£)**	**Total cost (£)**
General Medical Council	2012	£25	£6,060,000
Nursing and Midwifery Council	2012/13	£5	£3,590,000
General Dental Council	2012	£15	£1,573,000
General Optical Council	2012/13	£54	£1,150,507
General Pharmaceutical Council	2012/13	£9	£769,000
General Osteopathic Council	2012/13	£55	£258,839
General Chiropractic Council	2013*	£86	£249,000
Total		**£ 29 (average)**	**£13,650,346**

Source: Nursing and Midwifery Council, *Annual Report and Accounts 2012 – 2013* (2013); General Pharmaceutical Council, *Annual Report and Accounts 2012/13* (2013); General Dental Council, *Annual Report and Accounts 2012* (2013); General Medical Council, *Annual Report 2012* (2013); General Optical Council, *Annual Report and Accounts 2011 – 2012* (2013); General Chiropractic Council, *Council Meeting Reports, 8th August 2013*. *June 2013; General Osteopathic Council, *Annual report and* Accounts *2012 – 2013* (2013).

Using these figures, the average governance expenditure per registrant is £29. In the absence of a governance value for the Health and Care Professions Council we have derived a proxy[2] to give total governance expenditure by all 8 regulators of about £15.7 million. The costs per registrant are again highest for the smallest regulators in terms of registrant numbers, but there is more variation amongst the medium sized regulators.

[2] Using the 3 largest regulators – the Nursing and Midwifery Council, General Medical Council and General Dental Council – we derived the proportion of regulator expenditure in the 4 categories of interest as a percentage of each regulator's total expenditure. The proportionate rate was applied to the per registrant expenditure of HCPC giving a value of about £51 which was allocated across the four categories [governance, education, registration and fitness to practice] based on the ratio of the average expenditure per registrant.

Registration

In order to practise a chosen profession, a professional must register with the relevant regulator. For most professionals, their first contact in the regulatory system is at the point of registration. At this point, the regulator will check that the potential registrant has the relevant qualifications and experience to practise. Registrants will be required to renew their registration at regular intervals, at which point the regulators will have to check individuals' continuing eligibility for inclusion on the register. Some regulators will also maintain systems of revalidation and licences to practise, which will involve regular checks of practitioners' skills. Table 3 sets out the total costs to the regulators of performing their registration function, and the average cost per registrant.

Table 3: The registration costs of selected regulators

Regulator	**Period**	**Average registration cost per registrant (£)**	**Total cost (£)**
General Medical Council	2012	£73	£18,069,000
Nursing and Midwifery Council	2012/13	£8	£5,560,000
General Dental Council	2012	£19	£1,889,000
General Pharmaceutical Council	2012/13	£19	£1,585,000
General Optical Council	2012/13	£51	£1,103,377
General Osteopathic Council	2012/13	£30	£142,631
General Chiropractic Council	2013*	£4	£12,000
Total		**£29 (average)**	**£28,361,008**

Source: Nursing and Midwifery Council, *Annual Report and Accounts 2012 – 2013* (2013); General Pharmaceutical Council, *Annual Report and Accounts 2012/13* (2013); General Dental Council, *Annual Report and Accounts 2012* (2013); General Medical Council, *Annual Report 2012* (2013); General Optical Council, *Annual Report and Accounts 2011 – 2012* (2013); General Osteopathic Council, *Annual Report and Accounts 2012 – 2013 (*2013). *General Chiropractic Council Meeting Reports, 8th August 2013*. * end of year estimate for 2013.

Using these figures, the average cost of registration per regulator is £29**.** In the absence of a value for the registration costs of the Health and Care Professions Council, we have applied a proxy and derived a total value of about £30.4 million**.** It should be noted that the regulators' figures take into account the costs of different activities. For example, the General Medical Council has included revalidation in its registration figures, which may explain that its expenditure on this area is significantly higher than the other regulators. The General Pharmaceutical Council has included its customer service provision.

Education and standards-setting

An important part of the work of the regulators is the approval of courses provided by educational institutions such as universities or colleges, as well as ongoing, post-qualification education such as continuing professional development. The regulators will also be required to set standards and may publish supporting guidance. The following information is available on the education costs of the regulators.

Table 4: The education and standard-setting costs of selected regulators

Regulator	Period	Average education cost per registrant (£)	Total cost (£)
General Medical Council	2012	£28	£6,764,000
Nursing and Midwifery Council	2012/13	£5	£3,420,000
General Pharmaceutical Council	2012/13	£23	£1,428,000
General Optical Council	2011/12	£52	£1,119,483
General Osteopathic Council	2012/13	£101	£475,927
General Chiropractic Council	2013*	£26	£74,000
Total		**£38 (average)**	**£13,281,410**

Source: Nursing and Midwifery Council, *Annual Report and Accounts 2012 – 2013* (2013); General Pharmaceutical Council, *Annual Report and Accounts 2012/13* (2013); General Medical Council, *Annual Report 2012* (2013); General Optical Council, *Annual Report and Accounts 2011 – 2012* (2013); General Osteopathic Council, *Annual Report and Accounts 2012 – 2013 (*2013); General Chiropractic Council; *Council Meeting Reports, 8th August 2013*. *end of year estimate for 2013

Using these figures, the average cost of education and standards-setting per registrant is £38. In the absence of education and standard-setting costs for the Health and Cares Professions Council and the General Dental Council, we have applied a proxy based on a similar approach used in governance and derived a total education/standard-setting value of about £19.6 million**.** The average costs per registrant illustrated in the table do not follow any pattern according to registrant numbers, as the two smallest regulators have the highest and almost the lowest average costs. However, it should be noted that the figures do not allow a like with like comparison. For example, the General Pharmaceutical Council has included education and continuing professional development.

Fitness to practise

When a professional falls below the standards set by the regulator, the latter must take action to protect the public. This is the purpose of the fitness to practise procedures at the regulators. This function requires the regulator to investigate and adjudicate allegations that a practitioner's fitness to practise may be impaired, while respecting the requirements of procedural fairness such as independence and impartiality. All regulators have fitness to practise panels, sometimes referred to as a fitness to practice committee.

Fitness to practise panels usually consist of three persons and include a mix of lay and registrant members. There may also be a legal assessor to advise on the law and legal procedure and other specialist advisers. In 2007, it was estimated that approximately 1000 fitness to practise panel members were required to enable all the regulatory bodies to perform their fitness to practise function. The predicted costs of retraining were set at £350,000.[3] Five of the regulatory bodies within the scope of this project currently have about 900 panellists.[4] Different arrangements exist within each body regarding

[3] Source: Department of Health, *Trust, Assurance and Safety – Partial Regulatory Impact Assessment* (2007)

[4] Over 400 panellists on the Nursing and Midwifery Council, 271 on the General Medical Council – as well as 93 legal assessors; 136 panellists on the General Dental Council and about 77 panellists on the General Pharmaceutical Council and the General osteopathic Council.

remuneration rates and approaches to training. For example the Nursing and Midwifery Council pays an average cost of £500 for panellist training. Some regulators rely on in-house lawyers and their own facilities for training, for example the General Medical Council. The most significant training expense is the daily panellist fees, averaging around £300. If training is out-sourced it attracts a significantly greater expense.

There can be significant legal costs, as well as the costs of renting and maintaining appropriate premises and the general case management required to handle a case effectively. Furthermore, many regulators are currently unable to recover costs from registrants who are found to have impaired fitness to practise.

Fitness to practise costs form a significant element of the regulators' expenditure. Table 5 sets out the available information on the fitness to practise costs of the regulators:

Table 5: The fitness to practise costs of selected regulators

Regulator	**Period**	**Average fitness to practise cost per registrant (£)**	**Total cost (£)**
Nursing and Midwifery Council	2012/13	£70	£47,490,000
General Medical Council	2012	£168	£41,296,000
General Dental Council	2012	£141	£14,323,000
General Pharmaceutical Council	2012/13	£38	£3,208,000
General Optical Council	2011/12	£144	£3,088,541
General Chiropractic Council	2012*	£245	£689,000
General Osteopathic Council	2012/13	£117	£549,871
Total		**£132 (average)**	**£110,644,412**

Source: Nursing and Midwifery Council, *Annual Report and Accounts 2012 – 2013* (2013); General Pharmaceutical Council, *Annual Report and Accounts 2012/13* (2013); General Dental Council, *Annual Report and Accounts 2012* (2013); General Medical Council, *Annual Report 2012* (2013); General Optical Council, *Annual Report and Accounts 2011 – 2012* (2013); General Osteopathic Council, *Annual Report and Accounts 2012 – 2013 (*2013); General Chiropractic Council, General Chiropractic Council; *Council Meeting Reports, 8th August 2013*. * end of 2012 registrant numbers = 2808.

With the exception of the General Chiropractic Council and the General Osteopathic Council, the ranking of regulators by the total cost of fitness to practise mirrors the ranking of the regulators' number of registrants. However, the average costs per registrant do not follow that pattern so closely, which may indicate that some regulators are managing cases more efficiently. It is not possible to reach a firm conclusion because of variations in the cost elements of fitness to practise figures. For example the Nursing and Midwifery figure includes staff costs and related overheads whilst the General Medical Council's figure covers it investigation and prosecution activities, but excludes the Medical Practitioners Tribunal Service's costs of £8,150,000. In the absence of a value for the Health and Care Professions Council we have applied a proxy and derived a total value of about £121.0 million.

Costs of other litigation related to fitness to practise

Built into the statutory schemes of all of the regulators is an entitlement for the registrant concerned to appeal fitness to practise decisions to the higher courts. There are also costs associated with the renewal of certain interim sanctions which can require court orders. There are similar arrangements in Scotland and Northern Ireland. The regulators are also amenable to judicial review.

It is difficult to estimate the exact costs of litigation because the elements of each case vary. For instance, the length of the hearing and number of lawyers involved may vary. Furthermore, where a regulator is successful, the normal rule is that, as the losing party, a professional would normally be ordered to bear the costs of the appeal. However, the regulators report differing experiences of when such an award is effective, due to the difference in financial resources between the members of different

professions. See table 6 below for the number of final fitness to practise decisions made by the regulators in 2012 – 2013, and the number which were subject to an appeal to the higher courts.

Table 6: Number of cases concluded and appealed

Regulator	Period	No. of final fitness to practise panel decisions	Appeals received
General Chiropractic Council	2012/13	11	0
General Dental Council	2012/13	161	8
General Osteopathic Council	2012/13	9	0
General Medical Council	2012/13	209	40
General Optical Council	2012/13	28	2
General Pharmaceutical Council	2012/13	61	5
Health and Care Professions Council	2012/13	250	4
Nursing and Midwifery Council	2012/13	1280	16

Source: Professional Standards Authority, *Performance Review Report 2012 – 13* (2013)

This table gives an indication of the number of appeals made against the final fitness to practise decisions of each regulator in 2012/13. There is insufficient data available to be able to assess accurately the proportion of such appeals that are likely to be successful, and so the likelihood of the regulators' recovering their costs. The most that we can say is that the cost of appeals arising from fitness to practise decisions is in the region of [data awaited] based on there being 75 appeals in a year, at an average cost of [data awaited]. It is not possible to say with any certainty where the majority of these costs fall, but it will be split between the regulators, the Professional Standards Authority, registrants, and defence associations.

We also note that judicial reviews and interim order applications will increase the litigation costs in this area.

Annual expenditure by government on the regulators

An important aim of the review is to reduce the role of Government in maintaining the legal framework in respect of health and social care regulation. Currently, the majority of the Department of Health's activities in this area concern:

1. Amending the regulators' governing legislation by Orders of Council (Section 60 Orders), which are subject to Privy Council approval and Parliamentary scrutiny; and
2. Supporting the regulators' exercise of their rule and regulation-making powers, the vast majority of which require Privy Council approval, and some of which have to be laid in Parliament

The Department of Health engages in the process of rule formulation and development with eight regulatory bodies (in Northern Ireland, the Department of Health, Social Services and Public Safety Northern Ireland works with the Pharmaceutical Society of Northern Ireland on this issue). Accordingly, the Department of Health will benefit from significant economies of scale. Information provided by the Department of Health suggests that the annual handling costs of health and social care professional regulation legislation are approximately £793,000.

The costs per year cover the requisite policy and legal staffing, including any expenses. The Department has broken the costs down by different type of legal instrument, and estimates the following activity and costs each year:

1. 1.5 section 60 Orders with an estimated cost of about £269,000;

2. 5 regulatory body rules (Orders in Council) with an estimated cost of about £168,000 ;and
3. 5 government regulations with an estimated cost of about £356,000.

Options description

Two options have been considered:

- Option 0 – do nothing
- Option 1 – simplification and reform, as proposed in the Consultation Paper.

Initially, we also considered another option which was to retain and amend the governing legislation of the regulators. We did not proceed to develop this option because we concluded that this option would not fulfil our policy objectives of establishing a simple, consistent, flexible, accountable and efficient modern legal framework. It would also be virtually impossible to future proof and would take up a significant amount of Parliamentary time and resources, on an ongoing basis, to implement.

Option 0 – Do nothing

This option would mean retaining the existing legal structure for professional regulation. Some of the key features of the current law, which give rise to the issues identified earlier, are highlighted in table 7 below.

Table 7: Key features and associated problems of current legislative provision

Key Features	Associated problems
Separate governing legislation for each regulator	Detailed and highly complex legal system; Inconsistencies between the regulators' powers and duties
Key powers and duties contained in primary legislation	Inflexible; Changes require new primary legislation or lengthy section 60 order process
Privy Council approval required through the Department of Health for changes to legislation and rules	Inflexible; Delay; Lack of clear lines of accountability
Variation between the regulators' main duties	Lack of clarity; Lack of clear focus on patient safety (public protection put at risk)
Piecemeal development and extensive government oversight	Inefficiency; Expensive for regulators to operate and regulators to maintain
Increase in joint working and professional interrelationships, and the sophistication of interfaces in the health and social care sector	Current legal structures inhibit joint working and cooperation

In addition to the individual problems identified in the table above, the cumulative effect of the inflexibilities and complexities in the current system is the imposition of significant operational costs and delays caused by structural inefficiencies and this adversely impacts on patient safety.

Option 1 – Simplification and reform

The main recommendations are set out in the Law Commissions' final report under 13 separate parts, the key features of which are summarised below.

A key feature of the recommendations and draft Bill for the purposes of this assessment is that they impose a combination of powers and duties on both the Secretary of State to make regulations, and on regulators to make rules. It is intended that the duties will promote consistency where appropriate. The powers will enable flexible and efficient regulation.

Structure of reform and accountability (Part 2 of the Report)

Part 2 considers a number of preliminary matters which concern how the new legal framework should be structured and how the health and social care professional regulators should be made accountable for the exercise of their powers.

We recommend that the regulators' existing governing legislation would be repealed, and replaced with a single Act of Parliament to provide the legal framework for all of the regulators. Under our reforms, there would be consistency across the regulators where it is required in the public interest. Otherwise, the regulators would be given greater autonomy to adopt their own approaches to regulation in the light of their circumstances and resources. This would include broad powers to make or amend rules concerning issues such as registration and renewals, and education, standards and continuing professional development without any direct oversight, by the Privy Council or Government (subject to certain safeguards).

There would be a requirement on the regulators to consult when considering changes to their rules and a requirement that each regulator must provide information to the public and registrants about its work. The role of the Government would be clarified. Accordingly, the formal role of the Privy Council would be removed and the order-making power in section 60 of the Health Act 1999 would not apply to the new legal framework (but replaced with an equivalent provision). The Government would be given regulation-making powers on certain issues, and would retain its default powers where a regulator has failed to perform any of its functions.

General objectives (Part 3 of the Report)

Part 3 considers the main duties and general functions of the regulators and the Professional Standards Authority We recommend that the regulators and the Authority should be subject to a consistent main objective to protect, promote and maintain the health, safety and well-being of the public. The regulators would also be required to promote and maintain public confidence in the profession and proper professional standards and conduct.

Governance (Part 4 of the Report)

Part 4 considers the governance arrangements for the regulators. We recommend that the current structure of the regulatory bodies and the Professional Standards Authority's Board should be retained, but that they should be encouraged to focus on strategic, rather than operational, issues. The draft Bill specifies that most functions could be delegated to staff, and others.

We recommend that the Secretary of State be empowered to make regulations to provide for the constitution of the regulatory bodies and Professional Standards Authority's Board. The draft Bill specifies that a majority of members cannot be registrants, and provides a new definition of registrant and lay members.

Registers and registration (Part 5 of the Report)

A key statutory function of the regulators is to establish and maintain a register of professionals. Registration refers to the compilation of a list of individuals (and sometimes businesses) who have satisfied a regulator that they are qualified and fit to practise.

We recommend that there should be a core duty on all the regulators to establish and maintain a professionals register, and to continue to appoint a Registrar. The Government would be given a regulation-making power to add, remove or alter parts of the register, and to introduce other registration systems. We recommend that regulators should be prohibited from running voluntary registers, but that the Professional Standards Authority should retain its accreditation function.

The draft Bill requires the regulators to communicate expeditiously with registrants and potential registrants. Otherwise, they would be given broad rule-making powers concerning the processing of registration applications. There would be a requirement to establish a formal appeals process. These processes would be supplemented by a further right of appeal to the High Court in England and Wales, the Court of Session in Scotland, and the High Court in Northern Ireland.

There would be minimum requirements as to the content of the register, and a requirement to consult on the proposed use of annotations. There would also be a requirement that all current and many past fitness to practise sanctions to appear in the public register.

The current schemes of protected titles and functions would be maintained, and subject to amendment only by the Government. The regulators would continue to have powers to bring private prosecutions to enforce the protection of professional titles and functions.

Education, conduct and practice (Part 6 of the Report)

Our new system would impose duties on regulators to determine professional and education standards. We recommend giving the regulators powers to approve, and withdraw approval of, a range of matters relating to education. There would also be powers to make rules on rights of appeal, and systems of visitors. These rules would be supplemented by associated publication requirements. The regulators will also be required to determine standards of continuing professional development.

There would be a power for the regulators to issue guidance, and to indicate the status of such guidance. The establishment of new systems of revalidation will require Government regulations. Where revalidation is introduced for regulators, it will need to be accompanied by the introduction of a licence to practise scheme.

Fitness to practise - Impairment (Part 7 of the Report)

We recommend that the current three-stage test of impairment should be retained, but with some clarifications of the terminology used to describe the statutory grounds. The grounds will be:

1. deficient professional performance
2. disgraceful misconduct
3. inclusion of the person on a barred list
4. a determination by another regulator to the effect that fitness to practise is impaired
5. adverse physical or mental health
6. insufficient proficiency in the knowledge and use of the English language
7. convictions or cautions
8. certain other court disposals

Fitness to practise - Investigation (Part 8 of the Report)

We recommend that the regulators should refer any case for preliminary consideration where an allegation is made that a professional's fitness to practise is impaired or the regulator otherwise has reason to believe that the professional's fitness to practise is impaired. The draft Bill specifies that certain cases cannot proceed beyond preliminary consideration (such as vexatious allegations or where 5 years has passed since the incident or allegation – unless it is in the public interest to proceed). Regulators would be required to refer certain cases directly to a fitness to practise panel (for example, certain criminal convictions), and the draft Bill also creates a presumption of removal in respect of the most serious criminal convictions.

The regulators would be given flexibility as to how to investigate allegations. The draft Bill gives all the regulators a general power to require the disclosure of information where the fitness to practise of a registrant is in question. The test for all referrals to a fitness to practise panel across the regulators would be the realistic prospect test. The draft Bill expands the range of disposals available at the investigation stage. For example, the regulators will be able to issue warnings and agree undertakings following an investigation. The draft Bill also enables each regulator to initiate a review of certain investigation decisions where the case has not been referred to a fitness of practise panel.

Fitness to practise - Adjudication (Part 9 of the Report)

The draft Bill specifies certain procedural elements that we consider necessary to ensure compliance with article 6 of the European Convention on Human Rights. All fitness to practise hearings will be required to be conducted by at least 3 members (including at least one lay member). The draft Bill also requires the regulators to establish a body or person responsible for appointments, appraisal and continued development of panellists. .

The regulators would have a broad power to establish rules for pre-hearing case management. Each fitness to practise panel will be given the general objective of dealing fairly and justly with cases (as well as the general objectives in clause 3). There would be a duty on regulators to comply with a request that

a hearing takes place in the UK country where the registrant resides or incident took place, unless there are reasons that justify refusing the request. The civil rules of evidence, and the civil standard of proof are applied to hearings. The draft Bill provides that most hearings will be in public except for interim order and health cases. There will be a single consistent definition of witnesses who are eligible for special measures.

Certain procedural matters will be imposed on all fitness to practise hearings, such as the right to representation, witness summons and powers to join cases. In addition, The Government will be given a power to give guidance about fitness to practise procedures, including in the form of model rules.

All fitness to practise panels will have the same powers t impose sanctions or otherwise dispose of cases. The sanctions would be advice, warnings, conditions, suspension and removal from the register. All panels would be able to agree undertakings and voluntary removal, and issue immediate orders pending the outcome of any appeal to the higher courts. The statutory right of appeal against a panel decision of a fitness to practise panel to the High Court in England and Wales, the Court of Session in Scotland and the High Court of Justice in Northern Ireland would be maintained.

The regulators would be required to establish a system for imposing and reviewing Interim Orders .The right of appeal against an Interim Order to the High Court in England and Wales, the Court of Session in Scotland and the High Court of Justice in Northern Ireland would be maintained. The regulators would be required to have a system for reviewing certain sanctions.

Overlap issues (Part 10 of the Report)

The draft Bill provides that any two or more regulators should be able to arrange for any of their respective functions to be exercised jointly. The Professional Standards Authority will be required to promote such co-operation. Each regulator will have express powers to delegate most of their functions to another regulator or any other person. Furthermore, there would be two concurrent duties to cooperate – a general duty and a specific duty. The regulators will be required to co-operate with each other, the Professional Standards Authority and specified “relevant authorities”. When a regulator requests the co-operation of a relevant authority (or when such an authority makes a similar request of a regulator), the requested body would be required to comply unless doing so would be incompatible with its duties or have an adverse impact.

Premises and business regulation (Part 11 of the Report)

Our system would maintain the existing provisions for premises and body corporate regulation applicable to the General Pharmaceutical Council and General Optical Council. The Government would be given powers to reform these systems and extend business and premises regulation to any other regulator. We also recommend that the regulators would be able, subject to the Professional Standards Authority’s approval, to allocate funds to another organisation to investigate and resolve consumer complaints about registrants.

Professional Standards Authority (Part 12 of the Report)

We recommend that the general powers and functions of the Professional Standards Authority should be extended to include promoting economic efficiency and cost effectiveness by the regulators. The Authority’s power to give directions to the regulators will be enacted in the draft Bill. It would also continue to be able to accredit voluntary registers maintained and operated by bodies other than the regulators, and would continue to provide advice or undertake investigations on when requested to do so by the UK government and devolved administrations. We also recommend that the Government would have the power to make regulations enabling the Authority to investigate complaints made to it about the way in which a regulator has exercised any of its functions. The Authority’s power to refer fitness to practise cases to the higher courts would be retained.

Other issues (Part 13 of the Report)

The regulators will be required to carry out a public consultation before they make or issue rules, standards or guidance. All protected titles and functions, and relevant offences, are set out on the face of the draft Bill. The Nursing and Midwifery Council would retain its obligations to make rules regulating the practice of midwifery.

Cost benefit analysis

This impact assessment identifies both monetised and non-monetised impacts of intervention, with the aim of understanding the overall impact on society and the wider environment. The costs and benefits of each option are measured against the "do nothing" option. Impact assessments place a strong emphasis on valuing the costs and benefits in monetary terms. However there are important aspects that cannot sensibly be monetised. These might include impacts on equity and fairness, either positive or negative, or enhanced (or diminished) public confidence. A screening document which considers equality issues has been produced and accompanies this impact assessment.

The impact assessment process requires that we make an assessment of the quantifiable costs and benefits even when there is insufficient material on which to base those calculations. Where possible we have spoken to stakeholders to inform our view of the likely impact of our proposals and have used this as the basis for our calculations. Where it has not been possible to obtain a rough indication of numbers in this way we have had to make a realistic estimate. In such cases we have taken a conservative approach and have tended to use figures that we considered likely to under-estimate benefits and over-estimate costs.

When calculating the Net Present Values (NPVs) for the impact assessment we have used a time frame of ten years, with the current year (2013) being year 0. We have assumed that the transitional costs and benefits occur in year 0, and ongoing costs and benefits accrue in years 1 to 10. A discount rate of 3.5% has been used in all cases in accordance with Treasury guidance. Unless stated, all figures are in 2012-13 prices, and have been uprated using the GDP deflator.

Option 1 – simplification and reform

A key feature of the proposed programme of reform is that the draft Bill imposes consistency in a small number of key areas, but otherwise confer a number of regulation and rule-making powers on be exercised by the Government and regulators. This is intended to create a framework within which Government and the regulators can develop flexible approaches to regulation.

We are unable to predict with certainty which powers will be used, and cannot control whether they will be used in a way that produces costs or benefits. However, we anticipate that statutory duties to consult before exercising the powers, including on impact assessments where relevant, as well as oversight of the regulators by the Professional Standards Authority will encourage their rational exercise. We, therefore, estimate that it is highly probable that (a) the regulators will continue to perform their functions and (b) a rational regulator is likely to seek efficiency savings to the fullest extent, subject to this not impacting on the overarching duty to promote and protect public safety. We consider that an average range of 2% - 10% (best estimate 5%) level of efficiency savings is plausible across the regulatory framework. The conservative percentages applied reflects the on-going programme of reform throughout the sector which means that in some areas efficiency gains have already been secured ahead of proposed recommendations.

Costs

Transitional costs

1. Appointment of panellists

Regulators will be required to establish a body responsible for the appointment of, and ongoing engagement with, panellists who will sit on registration appeals, interim orders, and final fitness to practise panels. For those regulators that do not already have such a body, there will be one off costs associated with the establishment of the body itself.

2. Training of panellists

We do not anticipate that the costs of substantive activities relating to panellists will increase. There may well be one-off costs associated with retraining panel members at the regulators. The Medical Practitioners' Tribunal Service thinks that any retraining could be accommodated within existing time allocations, whereas the Nursing and Midwifery Council has suggested that the time and costs of retraining could be more significant.

We do not consider that there would be an added on-going burden because the most important procedural and evidential elements will be specified in the draft Bill and so not subject to regular change. The regulators also already have embedded training schemes. See table 8 below.

Table 8: Training costs

	Low estimate	Best estimate	High estimate
A. Average daily expense	£30	£40	£50
B. Additional number of training days	1	1	1
C. Average daily fee	£300	£300-£500	£500
D. Number of panellists	400	750	750
Total BD(A+C)	£132,000	£330,000	£412,500

Assumptions:

- Average panellist expense [travel/subsistence] for one day = £30 to £50[5]
- Cost of training day: daily hearing fee range £300 to £500, where upper range includes cost of out-sourced training provision
- Additional number of training days – 1 day
- Number of panellists requiring additional training days, 400 to 750, with 750 being best estimate
- Best estimate is based on a maximum number of 750 panellists with 375 costing £300 and 375 costing £500
- General Medical Council will not require any additional training days[6]

On-going costs

3. Increased marketing arrangements

In addition to training panellists, the regulators will also need to promote the effects of the reforms on their activities more generally. This may result in an increase in the costs of marketing and publicity activities but this is expected to be negligible and capable of being included alongside existing arrangements.

4. Creating and implementing new rules and regulations

Under our proposed scheme, the regulators will have powers to make rules in a greater number of areas than at present. The requirement for Privy Council approval of such rules (including Government input) will be removed. The regulators will simply make and adopt their own rules, without Government oversight. In terms of numbers, the regulators will be required to make rules on approximately 20 issues and will have powers to make rules in approximately 30 additional areas. However, there is scope for economies as not all require separate instruments.

The costs associated with the creation of rules include will include developing policy, legal advice, drafting. We have received evidence from some regulators that they already undertake a lot of the development work for rules and regulations that are eventually become secondary legislation at present, and so the removal of the role of the Government will not mean that all of the costs that it currently incurs will be transferred to the regulators. However, the increased volume of rules and the lack of any Governmental resource will lead to some increase in costs to the regulators. There is likely to be a difference in the capacity between large and small regulatory bodies such that the small regulators may face the greatest increase in legal costs and may need to buy in specialist expertise, either by employing additional staff or commissioning extra legal services. There will also be some additional costs arising

[5] Uplift to reflect national panellist pool based on Hansard note of average industrial expense claim size in region of £10 [18th March 1997)

[6] Based on consultation response

from the consultation duty. However, as regulators tend to run online consultations, we think that the majority of costs associated with consultation would fall under the umbrella of policy development.

5. Extra activity arising due to clarifying access to the regulators' fitness to practise mechanism (widened systems / information**).**

Part of our scheme includes a requirement on the regulators to clarify how an allegation of impaired fitness to practise can enter the regulatory system. In particular, there would be no restrictions on the content of information received, format of an allegation or time limit within which an allegation could be brought. We envisage that this may lead to a small increase in the numbers of allegations that enter the fitness to practise system, as we do not believe that many allegations are screened out on technical grounds.

We also recommend in the final report that the regulators should be required to provide information about their work. All of the regulators have sophisticated publication schemes. Accordingly, we do not consider that this would incur extra costs.

It was suggested in response to consultation that changes to the rules relating to the investigation and adjudication of complaints, including the fact that some will be regulator-made rather than contained in legislation, will lead to increased litigation, as registrants test the effect of the new rules. As we are imposing more consistency, particularly in relation to those aspects relating to registrant's procedural rights, we do not think that this will lead to an increase in litigation costs. We have also concluded that the statutory grounds of impairment should be largely retained, partly in order to preserve the benefit of the settled case law. However, the range of decisions that the Professional Standards Authority will be able to challenge will increase, as it will include the new consensual disposals available at the investigation stage of the fitness to practise process. The Authority's accounts do not specify how much is currently spent on cases of this type, but we do consider that the legal costs of this increased activity will be significant. The Authority would have good prospects of recovering its costs in those cases in which it was successful, as the regulators, rather than registrants, would be the paying party.

6. Increased staffing requirements of the Professional Standards Authority

It is anticipated that the regulators will be responsible for funding the Authority by the time that any legislation resulting from our recommendations comes into force.

In addition to the potential additional legal costs referred to in the previous section, the increased number of decisions amenable to challenge by the Authority will require additional resources to scrutinise those decisions to determine whether a challenge is appropriate.

The Authority will also be expected to set standards, criteria and guidelines in respect of issues such as the regulators' duty to consult before making or amending rules, and the appointment of panellists. The Authority will also have to approve certain exercises of the regulators' powers, such as dispensing with the duty to consult and financing an independent complaints service. We do not recommend any reduction in the Authority's existing activities, so this additional work is likely to require increased resources in terms of staffing and expertise.

Table 9: Professional Standards Authority additional annual salary expenditure

Skills level	No. of staff	Median gross weekly salary [£]	Median gross monthly salary [£]	Plus 30% uplift [£]	Annual gross salary [£]
Administrative	1	393	1,572	2,044	24,529
Professional	2	1389	5,554	7,221	86,649
Total	**3**	**1,782**	**7,127**	**9265**	**111,178**

Assumptions:

- 3 additional staff members - 1 administrative and 2 professionals[7].
- 30 percent uplift to take account of full cost of appointment to the organisation

[7] Median salary category based on Annual Survey of Hours and Earnings [ONS]

A summary of the transitional and annual costs is provided in table 10 below.

Table 10: Summary of key costs

	Low estimate (£)	Best estimate (£)	High estimate (£)
Transitional			
Training	£132,000	£330,000	£412,500
Total transitional	**£132,000**	**£330,000**	**£412,500**
On-going			
Annual staffing cost Professional Standards Authority	£111,178	£111,178	£111,178
Present Value (Years 1 – 10)	£924,612	£924,612	£924,612

Benefits

On-going monetised benefits

The benefits associated with our proposed scheme can be grouped into two primary benefit themes. These include:

1. Efficiency savings for the regulators.
2. Decreased costs for government / public expenditure.

1. Efficiency savings for the regulators

A key element of our proposals is the possibility of allowing the regulators to introduce their own rules in a variety of different areas, particularly registration, education and standard setting and fitness to practise. We also intend that specifying certain matters in primary legislation will produce a more transparent and streamlined system, and give certainty in key areas. We intend that this will enable regulators to develop systems that are tailored to their needs, and so reduce unnecessary and disproportionate costs. The ability to specify set their own registration procedures and define the most appropriate way of dealing with investigations of fitness to practise are some examples.

An assumption made in this impact assessment is that a rational regulator will make rules that enable it to discharge its functions efficiently, and that this will result in some efficiency savings. We acknowledge that other change incentives exist, and that some regulators will already be operating cost efficient procedures. With the exception of governance estimates, we anticipate the potential for a range of savings being between 2% - 10% (best estimate 5%). In the case of governance, our original position has been revised and we will retain significant governmental oversight. In line with a conservative approach to the monetisation of benefits we have not derived an indicative range.

Applying these proportions to the overall spend indicated in tables 3, 4 and 5 yields the following efficiency savings to regulators, see table 11 below.

Table 11: Annual efficiency savings made by regulatory bodies

	Low estimate (2%)	Best estimate (5%)	High estimate (10%)
A. Registration	£608,886	£1,522,216	£3,044,432
B. Education and standards setting	£392,880	£982,199	£1,964,398

C. Fitness to practise	£2,397,588	£5,993,969	£11,987,940
D. Total annual efficiency savings	**£3,399,354**	**£8,498,385**	**£16,996,770**
E. Present value over 10 years	**£28,270,728**	**£70,676,819**	**£141,353,638**

We also anticipate that the inclusion in the draft Bille of express provisions relating to joint working and partnership arrangements will encourage regulators to work together in the discharge of their functions. The figures in the scale and scope section above illustrate that there may be efficiencies to be achieved by exploiting economies of scale.

2. Decreased costs for government / public expenditure

The Department of Health currently allocates about £793,000 to the maintenance of the legal framework relating to the regulation of health and social care professionals. Under our proposed scheme, some of this role would be removed. Therefore, there are savings to be made in this area.

The need for changes to governing legislation will be reduced by the draft Bill, which will update the legal framework and so address many of the problems that section 60 Orders are currently being used to remedy. The legislation will create approximately 12 Government regulation-making powers, which will be subject to similar procedures and laying requirements as section 60 Orders. They relate to things such as setting up new tribunal services or systems of regulation, and so in most cases would be likely to only be used on a one-off basis. The costs to the Department of making these regulations are likely to be similar to those incurred currently in relation to section 60 Orders. We expect that 3 of the regulation-making powers will be exercised at an early stage following adoption of the draft Bill.

The Government will also have a further 9e regulation-making powers, that will not be subject to the section 60 Order equivalent procedure. The costs to the Department of making these will be similar to those that it has provided for regulations.

There will, therefore, be savings on legal advice associated with policy formulation, drafting costs of initial proposals, internal departmental correspondence, approval procedure with the Privy Council, departmental submissions to the Secretary of State for Health in his or her capacity as a Privy Counsellor and laying procedures in Parliament (which requires drafting and publication of Explanatory Memoranda and any impact assessments). See table 12 below.

As noted above, the Government will no longer bear the costs associated with the development of the regulators' rules.

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Table 12: Decreased annual government expenditure

	Low estimate	Best estimate	High estimate
Less 'S60 equivalent' Orders	£26,917	£40,376	£53,834
Loss of rules function	£168,165	£168,165	£168,165
Reduced use of regulation-making powers	£177,773	£213,327	£248,882
Total	£372,855	£421,868	£470,881
Present value over 10 years	£3,100,849	£3,508,465	£3,916,082

Assumption:

- Less Section 60 equivalent orders will be required under the new system. We envisage a savings range of 10% - 20% (best estimate 15%) of total expenditure.

- Regulators now make and adopt their own rules removing the need for government support through the parliamentary process.

- The Department of Health is unlikely to routinely make use of regulation-making powers. This function will be limited to areas of significant public interest, we envisage savings of 50% to 70% (best estimate 60%).

Table 13 below provides a summary of the monetised benefits

Table 13: Summary of annual savings

	Low estimate (£)	Best estimate (£)	High estimate (£)
Efficiency savings	£3,399,354	£8,498,385	£16,996,770
Reduced Government expenditure	£ 372,855	£ 421,868	£ 470,881
Total per annum	£3,772,209	£8,920,253	£17,467,651
Present value over 10 years	£31,371,576	£74,185,284	£145,269,720

note - values to be rounded

Allocation of monetised benefits: efficiency savings will benefit the regulators; savings on government costs will benefit the government but represent a transfer of costs to the regulatory bodies.

Non-monetised benefits

The non-monetised benefits associated with a simple, consistent, flexible, accountable and efficient legal structure are a significant feature of our recommended scheme. In particular, there are three key themes which are apparent throughout our proposals:

1. Reduced risk to the public:
2. Improved information sharing: and
3. Increased public trust and confidence.

Reduced risk to the public

The primary purpose of the health and social care regulatory framework is to protect the public. The inclusion of this objective in clause 3 will ensure that it is at the core of all of the regulators' activities. Our system will give regulators the tools to ensure that proper standards of conduct are maintained, and that those falling below those standards have their right to practise restricted, in order to manage any risk to the public.

Furthermore, our scheme is intended to provide for a more flexible regulatory structure which would allow the regulators to adapt to changes in the professions which they regulate. A more dynamic legal structure will allow regulators to respond to new technologies and treatments, and so enable an improved regulatory response to evolving clinical contexts. The freedom to develop their own rules will allow regulators to develop processes that are appropriate to their specific needs, such as the investigation of fitness to practise. This will enable them to deal with cases more efficiently, including with less delays. Timely responses to concerns about registrants' fitness to practise will clearly promote public safety. The introduction of a review mechanism to the investigation procedure, and the extension of the Professional Standards Authority's right of challenge will also ensure increased scrutiny of

decisions about fitness to practise. New measures to ensure that all practitioners have the necessary English language skills to practise safely will also provide the regulators with another tool to ensure the protection of the public.

Improved information sharing

The recommended duties to co-operate and powers to work in partnership will assist information sharing between the regulators, and between the regulators and other bodies. This will enable any information about risks to public safety to be shared with all relevant organisations, and so should reduce the risk of incidents of concern falling through the regulatory net.

Increased public trust and confidence

Increased public confidence in the professions has long been recognised as a key objective of regulation. A clear and transparent system of regulation will promote this aim as the public will be able to understand it, and see that it is intended to promote their interests, rather than protect the reputation of the professions. The public is also more likely to make use of a system that it can understand. The obligations on regulators to publish information about the exercise of their functions, and the enhanced role of the Professional Standards Authority will also promote accountability.

We also consider that stricter definitions of registrant and lay members of the regulatory bodies, and the introduction of a separate body to appoint panellists will promote independence.

Summary of cost benefit analysis

This impact assessment has sought to identify some of the key costs and benefits that may be associated with our proposed scheme. Based on the figures presented we can summarise the envisaged best estimate position as follows in table 14 below:

Table 14: Summary costs/benefits in £million constant prices over a ten year period

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Costs											
Transitional	0.33	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
On-going	0.0	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11
Total	0.33	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11
Benefits											
Transitional	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
On-going	0.0	8.92	8.92	8.92	8.92	8.92	8.92	8.92	8.92	8.92	8.92
Total	0.0	8.92	8.92	8.92	8.92	8.92	8.92	8.92	8.92	8.92	8.92
Net benefit	-.33	8.81	8.81	8.81	8.81	8.81	8.81	8.81	8.81	8.81	8.81

Direct costs and benefits to business calculations (following OIOO methodology)

We do not anticipate any costs to business. The Law Commissions do not implement policy and is therefore out of scope of the one in, two out rules.

Part 3: Specific impact tests

An impact assessment must consider the specific impacts of a policy option upon various groups within society. These specific tests are carried out below and refer to the implementation of Option 1.

Statutory equality duty

We have conducted a screening exercise to determine whether a full Equality Impact Assessment is necessary. We concluded that it would be unnecessary to conduct a full Equality Impact Assessment. The screening document is appended to this impact assessment.

Competition

According to Office of Fair Trading guidance, the competition assessment must consider whether in any affected market, the proposal would directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete, or reduce suppliers' incentives to compete vigorously.

Having regard to these tests, we do not believe our recommendations will have any significant negative impact on competition. In particular, in the health and social care market, the regulatory burden is shared equally between competitors. Therefore, any tightening of regulatory standards would not put market actors at any relative competitive disadvantage.

Small firms

Many health and social care professionals operate as small businesses. In particular, chiropractors, dentists, osteopaths, opticians and pharmacists typically operate either as high street enterprises or on a self-employed basis. However, we do not believe our recommendations will affect adversely small business, their customers or competitors. Our recommendations focus on the means by which health and social care professionals are regulated, rather than the specific services they provide.

We have recommended a power to allow Government to enable regulators to regulate business premises. Although there may well be implementation costs associated with such an innovation, we believe that these would be off-set by improvements in standards and efficiency. However, an extension of business regulation would be the decision of the Government – following their own impact assessment.

Environmental impact and wider environmental issues

We do not foresee any impact on carbon emissions or on wider environmental issues.

Health and well-being

Our recommendations are expected to have a positive impact on health and well-being. A key objective of the proposals is to build a simplified and effective legal framework for the regulation of health and social care professionals. This will benefit public health and safety in all clinical contexts.

Human rights

The human rights dimension of our recommendations is most apparent in relation to our proposed reforms of the adjudication of fitness to practise cases. We have adopted the position that the regulators should be responsible for compliance with the Convention rights on a case-by-case basis. We believe that the maintenance of a full jurisdiction right of appeal will strengthen this.

In our view, our recommendations in relation to the composition of fitness to practise panels satisfy the requirements of impartiality and fairness required by Article 6 of the European Convention on Human Rights. We also consider our proposals in relation to the public nature of hearings will comply with Article 8 of the Convention, as fitness to practise panels will have the discretion to hold a hearing in private. Such a decision must be lawful and therefore must comply with Article 8.

Our ecommended reforms would comply with the objectives of promoting and protecting human rights under the Human Rights Act 1998.

Justice system

The impact on the justice system of our recommendations is considered throughout this impact assessment. In summary, our recommendations do not envisage any substantive new rights or duties which would increase the number of cases before the courts. In particular, we are maintaining the well-established routes of appeal to the High Court in England and Wales, the Court of Session in Scotland and the High Court of Justice in Northern Ireland.

We acknowledge that, in light of the 3% anticipated increase in complaints, there is a low level of risk that there may be more High Court appeals from fitness to practise panels. However, we consider that this would be at a level which is so low as to be not statistically relevant. This is because it does not follow that 3% more complaints will lead to an equally large increase in final fitness to practise decisions.

In general our recommendations are consolidations and simplifications of existing law and do not represent new duties. In those areas where we have put forward new duties, we have recommended that these be implemented through the introduction of regulations, if the Secretary of State wishes to do so. Therefore, it will be the decision of the Government – following their own impact assessment – whether to introduce new duties.

Accordingly, we do not envisage that our proposed reforms will impact the justice systems.

Rural proofing

We do not foresee any differential impact on rural areas.

Sustainable development

We do not foresee any implications for sustainable development.