Title: Health care and Associated Professions (Indemnity Arrangements) Order	**Impact Assessment (IA)**
IA No: 8037	**Date:** 3 April 2014
Lead department or agency: Department of Health	**Stage:** Final
Other departments or agencies:	**Source of intervention:** Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Sarah McKenzie (0113 254 6120)

Summary: Intervention and Options

RPC Opinion: Green

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**
-£2.9m	-£29.8m	£3.0m	Part	NA

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

Some regulated health care professionals in this country are currently practising without indemnity/insurance cover, or with insufficient cover. In these circumstances, patients would be unable to obtain compensation in the event of a negative incident negligently caused by the activities of a health care professional. Further, European legislation has come to force requiring Member States to ensure that systems of professional liability are in place on its territory.

What are the policy objectives and the intended effects?

The objective is to identify and put in place a system to ensure that those harmed by the negligent activities of regulated health care professionals have a means of redress. This is in accordance with the requirements of both our domestic policy that all regulated health professionals have cover in place and European legislation that requires only those health care professionals providing a service to visiting EU citizens seeking cross-border health care . This will be addressed with minimal impact on health professionals and the organisation for which they work.

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

Option 1 : Do nothing
Option 2 : Use existing legislation
Option 3 : Take a non-legislative approach
Option 4: Introduce new legislation across all the health care professional regulatory bodies

Option 4 is our preferred option as it alone fully meets the requirements of both our domestic policy and the Directive.

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	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** Unknown	**Non-traded:** Unknown	

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 Minister: Dan Poulter Date: 28/04/14

Summary: Analysis & Evidence — Policy Option 4

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	**PV Base Year** 2013	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** -£2.9m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£2.2m		£2.9m	**£31.3m**

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

- Cost to health professionals of insurance premiums. Excluding midwives, we estimate an annual cost to about 4,200 practitioners of £0.9m. These costs are in scope of OITO.
- For independent midwives, we estimate an annual cost to around 150 practitioners of £2.0m. There is a cost to set up social enterprises for independent midwives) to employ health professionals so that they will be able to obtain insurance (estimated cost of £1.5m over 2 years). Combined, these costs give an annual net cost to business of £2.0m and are outside the scope of OITO.
- Cost to regulatory bodies (which are not considered as businesses or civil society organisations) of implementing checks (estimated transition cost of £716k, with annual recurring costs (in each of the 10 years) of £80k)

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

- We have not identified any non-monetised costs.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£0m		£2.8m	**£28.4m**

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

- Patients, who bear the cost of adverse events both in terms of cost and personal impact, will benefit from new liability arrangements being in place. They will have access to redress for any harm they have suffered from the health care they have received. The full benefits accrue to these patients.

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

- Health care professionals who are not already covered by an indemnity arrangement will benefit from the assurance that, should they be involved in a negligent act that causes harm, they would be covered by an appropriate indemnity arrangement. Furthermore they, as individuals, would not be financially liable and so would not be in danger of losing personal assets. We have been unable to source reliable data to allow us to monetise this benefit.
- The presence of cover may well make the option of independent midwifery more attractive to potential clients (as it will be clear they have a route for redress), thus broadening choice. The requirement to hold insurance may also encourage membership of professional bodies, which would ensure that health care professionals are better linked in to the developments in their profession.

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

- We have assumed that, with no transaction costs, premiums will equate to pay outs in the long run, which in turn is the cost of the damage done. The transaction cost, which will include administration costs and a fair return (in the main for the risk taken on by insurance companies), will be compensated for by the security offered to patients and the insured (who avoid being made bankrupt). We have therefore assumed that the annual monetised benefits are equal to the annual recurring cost to practitioners.
- The lack and clarity of data around the cost to independent midwives has made determining the costs difficult.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	**In scope of OITO?**	**Measure qualifies as**

Costs: £3.0	**Benefits:**£0.0m	**Net:** £3.0m	Part	NA

Evidence Base

PROBLEM UNDER CONSIDERATION

1. There is a concern that some regulated health care professionals in this country are currently practising either without indemnity or insurance cover, or with insufficient cover. In these circumstances, patients may be unable to obtain compensation in the event of a negative incident negligently caused by the activities of a health care professional(s). This will result in costs for both patients and Government.

2. The UK Health Departments consider that individual tragedies caused by negligence should not be compounded by the inability to obtain compensation. The Finlay Scott review[1] was commissioned to help us to examine the most cost effective and proportionate means of achieving the policy objective.

3. In parallel to the development of our domestic policy, European legislation came into force requiring Member States to have in place requirements in relation to indemnity arrangements for those providing a service to visiting EU citizens seeking cross-border health care. The date for this legislation to be transposed into domestic legislation was 25 October 2013. The UK is now at serious risk of infraction proceedings.

4. We have combined the domestic policy and European requirements into one piece of legislation, in the spirit of reducing regulation as this would help us to avoid multiple regulations covering similar areas.

5. The problem under consideration is how to put in place a system to ensure that those harmed by the negligent activities of regulated health care professionals have a means of redress that is both cost effective and proportionate and meets the requirements of European Law.

[1] Independent review of insurance or indemnity as a condition of registration

BACKGROUND

Domestic concerns on lack of indemnity cover for regulated health care professionals

6. Domestic concerns about professional indemnity predate the introduction of the European Directive. In May 2003, Des Turner MP introduced a Ten Minute Rule Bill to require professional indemnity, following a case where a dentist who had harmed a patient had failed to take out indemnity. The Bill was rejected, but Rosie Winterton, then Minister of State for Health, wrote to Des Turner committing to explore options to address his concerns.

7. In March 2004, the then Minister of State for Health decided to proceed with compulsory indemnity for regulated health care professionals on the basis that individual tragedies caused by negligence should not be compounded by the inability to obtain compensation. Accordingly there was a proposal that legislation should be introduced on a regulator by regulator basis, but this was going to take a considerable amount of time and resource to complete.

8. There are 32 groups of regulated health care professionals (the health care professionals) who must be registered by one of nine statutory health care professional regulatory bodies in order to practise their profession. There is currently no consistency across the health care professional regulatory bodies with regard to legislation or guidance on the need for individual regulated health care professionals to hold insurance or indemnity cover (an indemnity arrangement).

9. In terms of the current position on insurance and indemnity, the health care professional regulatory bodies fall into three groups:

   a. Those whose guidance insists on insurance or indemnity (when in active practice) and it is a statutory requirement: the General Chiropractic Council (GCC), the General Optical Council (GOC) and the General Osteopathic Council (GOsC) and the General Pharmaceutical Council (GPhC);
   b. Those whose guidance insists on insurance or indemnity and a statutory requirement has been approved by Parliament, but is not yet in force: the General Dental Council (GDC), the General Medical Council (GMC) and the Pharmaceutical Society of Northern Ireland (PSNI); and
   c. Those whose guidance does not insist on insurance or indemnity, nor is it a mandatory requirement: the Health and Care Professions Council (HCPC) - previously the Health Professions Council - and the Nursing and Midwifery Council (NMC), although the NMC recommends it.

10. It should be noted that legislation in respect of the Pharmaceutical Society of Northern Ireland is devolved to the Northern Ireland legislature and is not addressed in the proposed Order.

11. The Department is aware that there continues to be cases outside of the NHS where indemnity cover has not been in place and any attempt by the patient to seek redress in court would not have resulted in compensation to the patient due to the lack of personal assets.

12. Given the issues of consistency across the health professions and lack of redress in some cases, the government welcomed the EU Directive.

EU Directive 2011/24/EU on patients' rights in cross-border health care

13. Following negotiations across Europe, the European Union Commission, Parliament and European Council formally adopted Directive 2011/24/EU on the application of patients' rights in cross-border health care (the Directive), via the co-decision process. Member States had until 25 October 2013 to transpose the Directive's requirements into their national laws and the UK is currently at serious risk of infraction proceedings for failure to implement fully.

14. The Directive sets out that, with regard to cross–border health care (citizens of other EU member states seeking health care in another member state), Member states should ensure that there are transparent mechanisms in place for patient redress for any harm they have suffered from health care they receive. Article 4(2)(d) says that Member States shall ensure that:

    'systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory'.

15. In its definitions, the Directive sets out that:

    'Article 3(a) 'health care' means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'

    And that:

    'Article 3(f) 'health professional' means a doctor of medicine, a nurse responsible for general care, a

dental practitioner, a midwife or a pharmacist within
the meaning of Directive 2005/36/EC, or another
professional exercising activities in the health care
sector which are restricted to a regulated profession
as defined in Article 3(1)(a) of Directive 2005/36/EC, or
a person considered to be a health professional
according to the legislation of the Member State of treatment'

16. For the purposes of this impact assessment, a regulated health care professional is deemed to be a health professional delivering health care as defined above.

OPTIONS APPRAISAL

17. We considered the options to do nothing, use existing legislation, take a non-legislative approach or introduce legislation. These are discussed below.

Option 1: Do nothing

18. The 'do nothing' option is not feasible as it would not address the concerns that some regulated health care professionals currently practise without indemnity or insurance cover, neither would it meet the requirements of the Directive. If no system is in place to ensure that all regulated health care professionals are covered by an appropriate indemnity arrangement for the purpose of the care they deliver to patients seeking health care across borders, the UK Government would be at risk of being fined by the European Court of Justice for a failure to implement the Directive. Therefore, in line with guidance from the Department of Business, Innovation and Skills, the 'do nothing' option has not been included in this Impact Assessment.

Option 2: Use existing legislation

19. Amending existing legislation would have perpetuated a piecemeal approach to the issue, requiring multiple sets of regulations (perhaps one for each regulatory body) that could otherwise be achieved via one piece of legislation. It would also cause a lack of consistency across the health care professional regulatory bodies. It would also mean that an absence of cover might only be discovered after an incident occurred. This would not meet either the policy objective or the requirements of the Directive. Accordingly further work was not undertaken on the proposal.

Option 3: Take a non-legislative approach

20. In line with cross-Government initiatives to reduce regulatory burdens, the Department of Health, on behalf of the four UK Health Departments, has fully explored whether non-legislative steps might achieve the same results. Principally, we have explored whether or not the health care

professional regulatory bodies' guidance to their registrants could require them to hold an indemnity arrangement. This would mean that a failure to do so would be treated as a fitness to practise matter and the health care professional regulatory body would respond accordingly.

21. We regarded this proposal as flawed as it did not ensure that a system of indemnity was in place and that failure to hold such cover would only be addressed in cases where its absence came to light. In light of this, the view was that this solution did not meet either the requirements of the Directive or the policy objective.

Option 4: Introduce new legislation across all the health care professional regulatory bodies

22. In considering this option we draw heavily on the findings of the Independent Review Group (made up of representatives from health care professional regulatory bodies, professional bodies, patient/public representatives and other interested parties)[2]. It was established in 2009 by the then Secretary of State for Health in England, with the support of Ministers in Northern Ireland, Scotland and Wales to make recommendations to Government as to whether requiring health care professionals to have an indemnity arrangement in place as a condition of their registration was the most cost effective and proportionate means of achieving the policy objective that all registered health care professionals have cover.

23. In order to assess the comparative costs and benefits of a statutory condition of registration, the Independent Review Group commissioned research from Pricewaterhouse Coopers to:
    - assess the scale and seriousness of incidence;
    - examine the costs and benefits of options for introducing insurance or indemnity as a condition of registration for regulated health care professionals; and
    - identify the practicalities of minimising associated costs to ensure that the impact is as proportionate as possible.

24. A lack of reliable data meant that the Independent Review Group were unable to formulate a conventional cost benefit analysis. Instead they used a method which considered the costs of:
    - compliance – the costs incurred by registrants in satisfying the requirement to have insurance or indemnity.
    - compliance testing – the costs incurred by regulators in determining whether registrants satisfy the requirement to have insurance or indemnity; and

[2] Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional – Annex A

- enforcement – the costs incurred by regulators when the requirement to have insurance or indemnity is not satisfied.[3]

25. After consideration of the issues the Independent Review Group concluded that:

> ‘making insurance or indemnity a statutory condition of registration is the most cost effective and proportionate means of achieving the *policy* objective’ [4]

26. The Independent Review Group also concluded that such a requirement would best work because:
    a. A statutory condition of registration would apply equally and unequivocally to all registered health care professionals; would be seen by patients and the public to do so; and would enhance patient and public confidence.
    b. A statutory condition of registration has the unique advantage that, when supported by appropriate powers, enforcement action can be taken through low cost administrative procedures rather than high cost fitness to practise procedures.
    c. As a result, a statutory condition of registration would reduce enforcement costs compared with alternatives, without increasing compliance costs or the costs of compliance testing.
    d. A statutory condition of registration would require the health care professional to be able to prove a positive, namely the presence of cover, rather than the regulator to prove a negative, namely the absence of cover.
    e. A statutory condition of registration creates the opportunity for action by the regulator before the event, through registration procedures, to ensure that insurance or indemnity is in place.[5]

27. We have therefore concluded that this option is the only feasible approach to addressing the problem. This option implements the key recommendations of the Independent Review Group through new legislation, consistent across all the health care professional regulatory bodies, which:
    - Introduces a requirement for health care professionals to have an indemnity arrangement in place (so also supports the requirement of Article 4(2)(d) of the Directive);

[3] Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page14

[4] Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page 3

[5] Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page 3

- Provides health care professional regulatory bodies with a power to make rules on:-
  - What information needs to be provided by health care professionals and when to confirm that they have an indemnity arrangement in place in order to practise;
  - A health care professional's responsibilities in relation to informing their health care professional regulatory body should cover under an indemnity arrangement cease; and,
  - A health care professional's responsibilities in relation to informing their health care professional regulatory body if the source of their indemnity arrangement is one provided by an employer;
- Gives health care professional regulatory bodies the ability to refuse to allow a health care professional to join, remain on, or return to, their register; and,
- Permits health care professional regulatory bodies to either administratively remove a health care professional from their register, or take fitness to practise action against them, in the event of there not being an appropriate indemnity arrangement in place.

28. It is proposed that this option will be implemented through the "Health Care and Associated Professions (Indemnity Arrangements) Order 2014" ("the Order") by requiring all statutorily regulated health care professionals who are practising to have indemnity arrangements which provide appropriate cover. If a health care professional is practising, and doesn't have appropriate cover, then the Registrar (in most cases) can remove them from the register, or if they want to be entered on the register, then the Registrar can refuse to do so. The effect is that holding indemnity cover becomes a condition of registration where a person is practising or is seeking to practise.

29. It is important to stress that there is no intention to introduce duplication through these proposals: if a health care professional benefits from an indemnity arrangement through their employer, and does not practise outside their employment, this would be sufficient to meet the requirement for registration as a health care professional. As the Independent Review Group put it:-

    'From the outset, there was an important distinction to be drawn in how the condition of registration could be met. For employees in the NHS or independent sector, it was intended that they should be able to satisfy the condition of registration by dint of the corporate cover that arises from an employer's vicarious liability for the acts or omissions of employees. As a result, personal cover, from a defence organisation, trade union or other body, would not be required in

relation to practice as an employee. Personal cover would only be required in relation to self-employed practice.' [6]

30. Furthermore, where individuals are covered through membership of a professional association which provides an indemnity arrangement that fully covers their scope of practice, this also would be sufficient to meet the requirement for registration as a health care professional.

How the Order meets the Directive requirements

31. The Independent Review Group's recommendations usefully provide a framework within which the provisions of Article 4(2)(d) of Directive 2011/24/EU can be implemented.

32. The Order is drafted to require individuals who are regulated as a health care professional and who are practising to have an indemnity arrangement in place as a condition of registration. It sets out that 'an "indemnity arrangement" may comprise —
    (a) a policy of insurance;
    (b) an arrangement for the purposes of indemnifying a person;
    (c) a combination of the two.'[7]

33. It is worth noting that :
    - The Order limits the requirement to regulated health care professionals who are *practising.* This means that only those who are working as a member of a regulated health profession and delivering health care will be caught by the Order.
    - The Order does not require those regulated health care professionals to secure additional insurance where they are already covered for their practice by an employer or by means of membership of a professional body which offers indemnity as a benefit. This is subject to the individual regulated health care professional confirming that the cover provided is appropriate to the nature and extent of the risk.
    - The Order sets the requirement but does not prescribe how that requirement should be fulfilled by the regulators or registrants.

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[6] Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 p 8

[7] Health Care and Associated Professions (Indemnity Arrangements) Order 2013

- To also meet domestic policy requirements, the Order will cover all regulated health care professionals treating patients in the UK and not just regulated health care professionals treating patients as part of cross border health care. We consider that it would be inequitable to provide EEA citizens with more favourable conditions of treatment than to UK citizens.

RISKS AND ISSUES

34. The initial Impact Assessment which was published alongside the consultation[8] document was drawn up using the best available data. However, as there was an absence of reliable data a series of assumptions were made. Accordingly the consultation document asked a series of questions and invited respondents to provide information to test the assumptions of the Impact Assessment. In the main the consultation responses did not provide any further concrete information to either disprove or validate the assumptions. However, we have had extensive follow-on discussions with independent midwifery groups and insurance professionals and, while these discussions only identified limited new information, this is reflected in our analysis.

35. As the scope of the Order is limited to individual regulated health care professionals, it does not address the question of indemnity cover for corporate health providers. Issues around corporate health providers have been addressed as part of the transposition of the other elements of the Directive, which were consulted on separately.

36. In November 2012 the Scottish Government completed a public consultation on the recommendations of the No-fault Compensation Review Group which it established in 2009. This Review Group recommended that all clinical treatment injuries that occur in Scotland; (injuries caused, for example, by the treatment itself or by a failure to treat, as well as by faulty equipment, in which case there may be third party liability) should be covered by a no-fault scheme. The Review Group also recommended that the scheme should extend to all registered health care professionals in Scotland, not simply to those employed by NHS Scotland.

[8] Health Care and Associated Professions (Indemnity Arrangements) Order 2013 https://www.gov.uk/government/consultations/protecting-patients-from-negligence

SUMMARY ANALYSIS OF PREFERRED OPTION

37. Based on our analysis, the main costs of policy implementation will be borne by self-employed healthcare professionals who currently practise without indemnity cover. Excluding midwives, there are estimated to be up to 4,195 of these practitioners with an overall annual cost of putting in place indemnity arrangements of £1.008m.

38. In addition, we estimate there are up to 154 independent midwives practising. In order for this group to continue practising in their preferred manner once the Order comes into force they will need to establish organisations with robust governance and protocols in place which will enable them to acquire indemnity arrangements. It is estimated that the total annual cost (undiscounted) to this group of indemnity cover would be £2.310m. In addition, the costs of establishing suitable organisations are estimated to amount to around £500k per organisation across the first two years. Two social enterprises have already been established and one more is in development. We estimate that these three social enterprises will be sufficient to cover the market and so the total setup costs of establishing social enterprises for independent midwives are £1.5 million across two years.

39. Additionally, those regulators who do not currently require indemnity as a requirement of registration have identified one-off and on-going costs for the administration of the system. We estimate the total costs of implementing the new arrangements to be £795k in year 0, £716k of which are one-off transition costs with annual recurring costs (in each of the 10 years) of £80k.

40. It is primarily patients who bear the cost of adverse events, in terms both of costs and personal impact, and it is those users who would benefit from liability arrangements being in place. Government will also bear some of the costs of care which could otherwise be paid for by indemnity arrangements. Benefits would also accrue to regulated health care professionals as their personal liabilities following an adverse event would be reduced.

41. As part of its work for an independent review group looking into the issue of insurance for regulated health care professionals, Pricewaterhouse Coopers made extensive efforts to source reliable data on the frequency and severity of the adverse events, but were unable to do so. It is clear that when these events do occur they will cause substantial stress and lead to significant additional costs for patients and the public sector.

42. The lack of this reliable data has made it impossible to produce specific monetised benefits. However we believe it is valid to assume that, with no transaction costs, premiums will equate to pay outs in the long run, which in turn is the cost of the damage done. The transaction cost, which will include administration costs and a fair return (in the main for the risk taken

on by insurance companies), will be compensated for by the security offered to patients and the insured (who avoid being made bankrupt). We have therefore assumed that the annual monetised benefits are equal to the annual recurring cost to practitioners of taking out indemnity cover (£3.3m in year 0).

43. In practice, the situation is a little more complex. If, when harm is done, and compensation is determined, in the absence of insurance there would be a payment from the health care professional to the harmed patient equal to the amount of the compensation. Large sums of money are at stake (in a recent NHS case £10.8m was awarded in compensation for the serious harm caused[9]). However, in such cases it is unlikely that the health care professional would be able to pay the full amount out of existing income and assets, and the health care professional would be made bankrupt. The patient would receive compensation at a level that equates to the assets of the health care professional concerned, and no more. This is analogous to the health care professional having 'free' insurance as a result of being able to declare bankrupt, with an 'excess' equal to his/her assets.

44. The cost of having to insure for the health care professions concerned is the amount of benefit they currently receive as a result of the 'free' insurance bestowed by bankruptcy arrangements. In theory one could estimate this if information were available on the difference between the compensation amount and the amount paid out by the uninsured (out of assets). However, because such events are rare and often settled out of court we have been unable to source such data for patients receiving health care from a self-employed health professional.

45. In extremis, in the absence of such information, we could assume that the uninsured has no significant assets, and makes a negligible contribution to any pay-out. In which case the full amount of the insurance (£3.3m in year 0) is a cost to business (and a benefit to the harmed patient).

46. However, this ignores the fact that

- bankruptcy itself is not costless - it will affect life chances (future income trajectory) and have stigma associated with it;
- there is the reassurance that if the worst happens, assets are protected (as most people are risk averse) and will have some assets (e.g. equity in a house) to protect;
- patients will have the security of knowing that, if the worst happens, there is cover and so this may improve the prospects for the businesses concerned.

47. That said, because of a lack of information on, amongst other things, the frequency of cases and the financial position of self-employed health care

[9] http://www.theguardian.com/society/2012/apr/30/girl-injured-birth-compensation-nhs

professionals, these benefits remain unquantified i.e. we have assumed here that the monetised benefits accrue solely to patients.

48. The following table shows the expected overall economic costs and benefits over ten years. The total estimated costs are £31.3m, and benefits £28.4m, which means a net cost of £2.9m over 10 years (discounted).

Table 1: Annual profile of monetised costs and benefits of preferred option (£m, constant (2012/13) prices, discounted)

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9	Total
Transition costs	*1.5*	*0.7*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*2.2*
Regulatory bodies	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7
Social enterprise set up	0.8	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5
Annual recurring cost	*3.4*	*3.3*	*3.2*	*3.1*	*2.9*	*2.8*	*2.7*	*2.6*	*2.6*	*2.5*	*29.1*
Practitioners (excl. independent midwives)	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7	8.6
Independent midwives	2.3	2.2	2.2	2.1	2.0	1.9	1.9	1.8	1.7	1.7	19.8
Regulatory bodies	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.7
Net present costs	4.9	4.0	3.2	3.1	2.9	2.8	2.7	2.6	2.6	2.5	31.3
Transition benefits	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*
Annual recurring benefits	*3.3*	*3.2*	*3.1*	*3.0*	*2.9*	*2.8*	*2.7*	*2.6*	*2.5*	*2.4*	*28.4*
Net present benefits	3.3	3.2	3.1	3.0	2.9	2.8	2.7	2.6	2.5	2.4	28.4
Annual net present value	-1.5	-0.8	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-2.9

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

49. We believe that there are additional non-monetised benefits. The presence of cover may well make the option of independent midwifery more attractive to potential clients (as it will be clear they have a route for redress), thus broadening choice. The requirement to hold insurance may also encourage membership of professional bodies, which would ensure that health care professionals are better linked in to the developments in their profession.

50. We have not identified any non-monetised costs.

Direct Impacts On Business

51. The direct impacts to business constitute:
    - The costs to individual health professionals of acquiring appropriate indemnity arrangements;
    - The transitional costs to independent midwives of establishing organisations through which they can acquire appropriate indemnity arrangements.

52. The costs to business (which excludes the transitional and annual costs to the Regulators (which were included in table 1 above) as these are not considered to be businesses) are shown below. The following table sets out the expected direct costs to businesses. As discussed above, the benefits to businesses remain unquantified.

Table 2: Annual profile of monetised direct costs and benefits to business of preferred option (£m, constant (2012/13) prices, discounted)

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9	Total
Transition costs	*0.8*	*0.7*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*1.5*
Social enterprise set up	0.8	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5
Annual recurring cost	*3.3*	*3.2*	*3.1*	*3.0*	*2.9*	*2.8*	*2.7*	*2.6*	*2.5*	*2.4*	*28.4*
Practitioners (excl. independent midwives)	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7	8.6
Independent midwives	2.3	2.2	2.2	2.1	2.0	1.9	1.9	1.8	1.7	1.7	19.8
Net present annual costs	**4.1**	**3.7**	**3.1**	**3.0**	**2.9**	**2.8**	**2.7**	**2.6**	**2.5**	**2.4**	**29.8**
Transition benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Annual recurring benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net present benefits	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Annual net present value	***-4.1***	***-3.7***	***-3.1***	***-3.0***	***-2.9***	***-2.8***	***-2.7***	***-2.6***	***-2.5***	***-2.4***	***-29.8***

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

EU v domestic elements of the proposal – additionally considerations

53. We have established, through our discussions with the Association of British Insurers (ABI) and through the findings of the Flaxman report (2011 report jointly commissioned by the Nursing and Midwifery Council and the Royal College of Midwives into the availability of commercial insurance for independent midwives), and it is generally accepted by practitioners in the sector, that the market will not provide insurance products for independent midwives working as individuals. However, the Flaxman report, and the information provided to the consultation by new social enterprises, have demonstrated that cover is available if the appropriate governance systems are in place.

54. We have been unable to source any information on the number of cross-border patients who are likely to use the services of independent midwives (we have been unable to extrapolate from NHS figures because visitors and migrants are not identified separately, nor are users of midwifery services), but the number will certainly be very low (given there are a maximum of 154 midwives seeing around 6-10 patients in total per year). The ABI have advised us that the very small number of patients over which to spread the risk coupled with the potential for significantly costly events (which could be over £10m of lifetime costs as in the example quoted above) means that, *even with social enterprises in place*, it is unlikely that the market would develop insurance products for independent midwives if just the EU elements of the proposal were implemented.

55. The same argument does not hold for the other 4,195 self-employed regulated health care professionals (nurses and therapists) who will be required to take out indemnity insurance. While the number of cross-border patients will again be low, the pool of practitioners is higher, the risks are lower and affordable commercial insurance is already available to cover the practitioners across the range of their work.

56. On the basis of this evidence, we have concluded that the costs to independent midwives would be no less if insurance were mandated for the EU elements alone, indeed there is the suggestion that insurance cover may not be available at all. In terms of incremental costs and benefits therefore, the domestic element extends the benefits significantly at little or no additional cost. The table below summarises the costs and benefits to business which remain in scope of One In Two Out i.e. self-employed regulated health care professionals not currently required to have an indemnity arrangement in place (excluding independent midwives).

Table 3: Annual profile of monetised direct costs and benefits to business of preferred option in scope of OITO (£m, constant (2012/13) prices, discounted)

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9	Total
Transition costs	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*
Annual recurring cost	*1.0*	*1.0*	*0.9*	*0.9*	*0.9*	*0.8*	*0.8*	*0.8*	*0.8*	*0.7*	*8.6*
Practitioners (excl. independent midwives)	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7	8.6
Net present annual costs	**1.0**	**1.0**	**0.9**	**0.9**	**0.9**	**0.8**	**0.8**	**0.8**	**0.8**	**0.7**	**8.6**
Transition benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Annual recurring benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net present benefits	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Annual net present value	***-1.0***	***-1.0***	***-0.9***	***-0.9***	***-0.9***	***-0.8***	***-0.8***	***-0.8***	***-0.8***	***-0.7***	***-8.6***

DETAILED ANALYSIS OF PREFERRED OPTION

Who will be impacted?

57. The following categories of groups will potentially be impacted by these proposals:
    - **Regulated health care professionals:** This group would be required to be sure that indemnity arrangements are in place. Some of them would bear the cost of obtaining cover.
    - **Employers of regulated health care professionals:** A limited indirect impact is possible, due to the potential that they may be asked to provide evidence of cover with associated administrative costs.
    - **Patients and the public:** This group would benefit by assurance that, should a negligent action by a regulated health care professional cause harm, recourse to redress was available, which may include financial compensation. Indeed research on public opinion commissioned by the Independent Review Group found that the majority of respondents thought that health care professionals were already required to hold an indemnity arrangement.
    - **The public and taxpayers:** In addition to the benefits for patients, this group would benefit by reduced costs to the public purse of meeting certain long term care and support services that are provided on a means-tested basis for patients following adverse incidents due to the negligent actions of health care professionals who do not have an indemnity arrangement in place.
    - **The health care professional regulatory bodies:** As the Independent Review Group envisaged there might be compliance testing and enforcement costs resulting from these policy proposals. As set out in the report of the Independent Review Group, the impact associated with enforcement is likely to be minimal or reduced as action could be taken via low cost administrative measures as opposed to high cost fitness to practise procedures. We sought information on the likely costs of compliance from regulators as part of the consultation and have amended this Impact Assessment accordingly. A more detailed analysis of the results from regulators is attached below.
    - **Providers of indemnity cover:** These are likely to experience changes to their margins due to the policies that individual health care professionals would be required to have an indemnity arrangement in place.

Estimating the number of health care professionals impacted by the policy

58. There are difficulties associated with estimating the number of health care professionals who are currently covered by an indemnity arrangement, and the source of that indemnity (e.g. an employer, professional body, or

personally held cover) due to an absence of reliable data. For the purposes of the consultative Impact Assessment, a series of assumptions were made using the best available data from a range of sources. The consultation document sought further information to test and validate these assumptions. Unfortunately for the most part this has not been forthcoming. A summary of our estimation procedure and the results is below.

59. Many professions are required (see Annex A for summary), either through guidance or legislation, to hold an indemnity arrangement. Of the professions identified, only those regulated by the HCPC and NMC are not currently required to have indemnity cover. The professions without cover are:
    - Practitioner Psychologists
    - Biomedical scientists
    - Clinical Scientists
    - Nurses
    - Midwives
    - Paramedics
    - Radiographers
    - Chiropodists/Podiatrists
    - Physiotherapists
    - Occupational Therapists
    - Speech And Language Therapists
    - Other therapists regulated by the HCPC (including, prosthetics and orthortists, orthoptists, operating department practitioners, arts therapists, dietitians and Hearing Aid Dispensers)

60. ONS figures (see Annex A for breakdown and source) show that only 167,000 of the 1.4 million health care professionals are self-employed. Health care professionals who are employed or engaged by the NHS or a private sector company will have an indemnity arrangement in place for that employment. Therefore, means of redress would naturally exist, so such individuals are considered to be out of scope for the impact analysis.

61. Of these 167,000 only 37,000 are in the professional groups (identified above) who are not currently required by their regulatory body to hold an indemnity arrangement, though they may do so. The employment figure for these groups is shown in the table 4 below.

62. The ONS classification of “Therapists not elsewhere classified” includes Osteopaths and Chiropractors who are already required to hold an indemnity arrangement. It also includes professions such as aroma therapists and hydro therapists who are not statutorily regulated and who are therefore excluded from this analysis. Table 4 includes a line for

"Therapists not elsewhere classified based on regulator data". This is based solely on data for the numbers of regulated health care professional therapists who are not currently required to hold an indemnity arrangement. This comprises data for Arts Therapists, Biomedical and Clinical Scientists, Dietitians, Orthoptists, Prosthetists and Orthotists, and Hearing Aid Dispensers. Using registrant data from the HCPC, the health care professional regulatory body responsible for these therapists, we have identified 12,173 self-employed individuals who fall within the definition of regulated health care professional therapist.

Table 4: Public and private employment figures for health care professionals not currently required to hold an indemnity arrangement, Jan-Dec 2010

	UK 000's		
	Private		
Professional group	**All**	**Employee**	**Self-Employed**
Psychologists	6	1	5
Nurses	83	80	3
Midwives	1	1	-
Chiropodists	6	0	6
Physiotherapists	14	5	9
Occupational Therapists	3	2	1
Speech and Language Therapists	2	1	1
Therapists NEC based on regulator data	15	2	12
Total	**130**	**92**	**37**

Note that any discrepancies due to rounding.

Therapists NEC based includes Arts Therapists, Biomedical and Clinical Scientists, Dietitians, Operating Department Practitioners, Orthoptists, Prosthetists and Orthotists, and Hearing Aid Dispensers, information from HCPC

Source: ONS (Labour Force Survey)

63. As part of the consultation we sought information which would enable us to assess whether the assumptions on numbers of individuals working in the private sector made in the consultative impact assessment were correct. The consultation did not provide much additional information. However, it was noted that the consultative Impact Assessment had omitted to list Hearing Aid Dispensers as within the scope of the assessment. In fact, this group was included in the calculation but had not been listed as being so. This has now been corrected.

Extent of non-employer provided indemnity arrangements

64. Of the 37,000 individuals identified some will be members of professional organisations which provide an indemnity arrangement as a benefit or require it as a condition of membership. Table 5 shows figures for this.

Table 5: Professional Body Indemnity coverage

Profession	Number of Registrants[1]	Number who are members of a professional body offering Indemnity Arrangements (excluding professional bodies where membership is currently unknown)[2]	% of practitioners covered via professional body membership (assumed 100% where no. of members exceeds no. of registrants)
Psychologists[3]	17,864	45,254	100%
Nurses	627,535	410,000	65%
Chiropodists	13,000	17,000	100%
Physiotherapists	46,479	51,250	100%
Occupational Therapists	31,928	29,000	91%
Speech and Language Therapists	13,175	14,000	100%
Therapists not elsewhere classified[4]	52,314	39,150	75%

Notes
1. Source: HCPC and NMC website September 2012
2. Source: Relevant professional body websites Summer 2012
3. Psychologists registered with professional body include a range of disciplines including educational and sports psychiatrists
4 Therapists NEC as for Table 4

65. As the table demonstrates the professional bodies for psychologists, chiropodists, physiotherapists and speech and language therapists provide indemnity arrangements for their members and have a membership larger than the regulated population. This indicates that 100% of individuals in these professions have indemnity arrangements in place.

66. There are a number of reasons why the membership of professional bodies may exceed the number of regulated individuals. These could include non-practising professionals remaining part of the professional body or where there is more than one professional association and registrants are members of more than one. In addition not all Psychologists are subject to statutory professional regulation but may be members of professional bodies.

67. For the other professions, we compared the number registered with professional bodies with the total numbers regulated to provide an estimate of the proportion of practitioners with indemnity arrangements in place. This suggests that 65% of nurses, 91% of occupational therapists

and 75% of therapists not elsewhere classified have indemnity arrangements due to their membership of a professional body.

68. Applying these percentages to the number of self-employed, private sector practitioners suggests that there are around 4,200 of these health care professionals without cover.

69. In addition, 154 registered midwives indicated that they intended to practise independently in 2013. Individual self-employed midwives are unable to secure indemnity cover through their professional body and we consider that none of these midwives are currently covered (further discussion on the position of independent midwives can be found below). Adding these to the figure for other regulated health care professionals without indemnity cover shows that there are a total of 4,349 regulated health care professionals practising without indemnity cover, as shown in table 6 below.

Table 6: Estimated number of self-employed regulated health care professionals without an indemnity arrangement.

Profession	**Number of self-employed, private sector practitioners, with therapists NEC based on regulator data**	**Estimated % of self-employed practitioners not covered via, or as a requirement of professional body membership**	**Estimated number of self-employed, private sector practitioners not covered via professional body membership, based on ONS data with therapists based on professional body/regulator data**
Nurses	3,000	35%	1,040
Midwives	154	100%	154
Occupational Therapists	1,000	9%	92
Therapists not elsewhere classified remaining in scope	12,173	25%	3,063
Total			**4,349**

Source: DH calculations

70. The figure of 4,349 is likely to include a number of practitioners who are covered by commercial insurance. However, neither Pricewaterhouse Cooper in their work on costs of indemnity, nor the Department have been able to source robust data on the number of practising regulated health care professionals with commercial insurance. In addition, a number of responses to the consultation indicated that some (unquantified) regulated health professionals identified as working in the public sector may also

undertake some work privately, and therefore require indemnity arrangements.

71. Given the paucity of evidence regarding numbers of self-employed regulated health care professionals who are covered by commercial indemnity arrangements or the numbers of regulated health care professionals identified as working in the public sector who also undertake private work the figure of 4,349 has been retained.

72. As part of the consultation we sought further information which we could use to evaluate the validity of the assumptions made in this Impact Assessment. Whilst we did not receive a large amount of information from the consultation which we could use for this purpose, the evidence received enabled us to:
    - Amend the IA to clarify that the calculations included 1,724 hearing aid dispensers
    - Confirm that for hearing aid dispensers the 75% figure for professional body membership is correct and that indemnity provisions are a benefit of membership.
    - Confirm that the membership of the Chartered Society of Physiotherapists is larger than the number of registered physiotherapists and provides a comprehensive package of indemnity to its members.

73. Consultation responses indicate that a higher percentage of Physiotherapists work in the private sector than indicated in the ONS figures. However, as the evidence shows 100% of practising physiotherapists have indemnity cover through professional body membership this will not affect the impact of the Order and we have therefore made no adjustments.

74. We received limited information on therapists not elsewhere classified. However information received from the British Association of Prosthetics and Orthotists indicates that around 33% of prosthetics and orthotists provide 'some private care'. This figure is close to the assumption in the consultative Impact Assessment that 31% of all therapists not elsewhere classified provide care in the private sector. In the light of this, the lack of information received for other groups of therapists and the relatively small number of prosthetics and orthotists it has been decided to retain the figure for therapists not elsewhere classified which is used in the consultative Impact Assessment.

ASSESSMENT OF COSTS AND BENEFITS

Estimating costs

Costs to health professionals

75. We identified that up to 4,349 regulated health care practitioners are without indemnity arrangements. Of these 154 are midwives who have declared to the NMC that they intend to practise in a self-employed capacity in 2013-14. This group are discussed in more detail below and are not included in the following calculations which estimate costs for the remaining 4,195 health care professionals.

76. We have collected information on the estimated cost of insurance from industry bodies and applied this to our estimates of the number of practitioners without cover. This is shown in the table below.

Table 7: Estimated annual cost of obtaining indemnity cover for practitioners without cover (excluding midwives)

Profession	Estimated number of self-employed, private sector practitioners without cover[1]	Estimated cost of insurance	Total estimated cost impact of professional body membership for professionals affected by the proposed new requirement
Nurses	1,040	£195[2]	£202,800
Occupational Therapists	92	£256[3]	£24,000
Therapists not classified elsewhere remaining in scope	3,063	£255[4]	£781,000
Total			**£1,007,800**

Notes:
1. Source: DH estimates – see earlier for calculation
2. Source. Royal College of Nursing website
3. Source: British Association of Occupational Therapists website
4. Source DH calculation of average cost for Therapists in scope.

77. The cost of £1,007,800 does not include the transaction costs to the registrant of obtaining cover, which are assumed to be negligible. The administrative costs of providing cover are included in the overall cost. Ultimately, it is likely that the additional cost to the registrant will be passed on to the patient.

78. We have assumed that all these costs are attributable to the domestic requirement to hold indemnity insurance. There are likely to be few cross-border patients and the relatively low cost and easy availability of commercial insurance (which contrasts with the situation for independent midwives) means that the costs of obtaining insurance solely for cross-border patients will be low. Given the lack of data on the precise number

of cross-border patients we have assumed the cost of compliance with the Directive to be zero.

Independent midwives

Background

79. There are in excess of 41,000 midwives registered with the Nursing and Midwifery Council (NMC), the vast majority of these midwives work in the NHS and will have indemnity cover via their employer. However, there is a small number of midwifes who work independently of the NHS. The NMC have informed us that 154 individuals registered with them have indicated that they intend to practise in a self-employed capacity in 2013-14. We do not have any details as to how many of these are full time, or how many will only offer services for part of the maternity care pathway as this information is not collected by the regulatory bodies.

80. It is recognised that there have been issues with some groups of independent providers, including groups of independent midwives, relating to their inability to purchase commercial insurance at an affordable price. Affordable commercial cover is not available to independent midwives working as individuals. The Flaxman report (2011 report jointly commissioned by the Nursing and Midwifery Council and the Royal College of Midwives into the availability of commercial insurance for independent midwives) concluded that although there was very little commercial appetite to insure individual independent midwives cover could be obtained as part of a corporate body or social enterprise.

81. Independent midwives work outside of the NHS chiefly for clients who want a home birth. Some work in social enterprises in collaboration with other self-employed midwives, but many work alone. There is a sub-group of independent midwives who are self-employed and are currently unable to obtain indemnity or insurance arrangements for the whole of the maternity care pathway.

82. The Department has engaged in discussion with a wide range of stakeholders including the Independent Midwifery sector over recent years and has been working to help this sector to identify a solution. We have identified several ways in which midwives will be able to obtain indemnity cover. The first is one where the Department has directly intervened. A corporate body that is employing midwives to provide NHS services (i.e. commissioned by a CCG) will be eligible to join the Clinical Negligence Scheme for Trusts (CNST), which is the scheme that indemnifies the majority of clinical negligence risks in the NHS, including overwhelming maternity risks. Membership of CNST was made available to all providers of NHS services, including independent midwives (apart from those under primary care contracting arrangements) from 1 April 2013. However, as the CNST scheme does not cover non-NHS work, it is argued that this does not help midwives that wish to remain ‘independent’ of the NHS.

83. Secondly, the Department has made funds available via its Social Enterprise Investment Fund (SEIF) to support the development of Social Enterprise solutions where the market does not offer affordable indemnity to individuals. SEIF is a Department of Health fund which provides investment to assist social enterprises delivering health and social care services.

84. A new social enterprise called Neighbourhood Midwives, was set up through this route and is now offering maternity care in the private sector with appropriate indemnity cover in place. Their business model is a 100% employee-owned mutual providing management and support to small, community based neighbourhood practices. We are also aware of other organisations that are pursuing a similar route, and are seeking funding via the SEIF to develop its model.

85. Some of the responses to the consultation have suggested that social enterprise models are not financially viable but we have been provided with information from social enterprises which indicate that this is not the case.

86. Discussions have also taken place with the Association of British Insurers, individual insurers and insurance brokers who have indicated insurance would be available for corporate bodies employing midwives to deliver NHS or non-NHS services. It would be necessary for corporate bodies to demonstrate the robustness of their governance systems to provide adequate assurance to an indemnifier. Where providers can demonstrate safe outcomes as well as good risk management processes, this would affect the price that is quoted making it more affordable. There are also other factors that can be varied depending on appetite for financial risk that can reduce the price, such as excess levels.

87. This concurs with the independent research commissioned by the NMC and Royal College of Midwives which suggests that independent midwives would be able to obtain insurance as employees within a corporate structure. There are independent midwifery providers who have secured insurance by fulfilling the above principles, one of whom is actually delivering services under a contract with the NHS.

88. There is a small body of independent midwives called Independent Midwives UK (IMUK), who represent approximately 80 self-employed independent midwives who are sole traders and individual practitioners running their own businesses. This is distinct from other independent midwives working in the private sector who are organised into groups in legal entities such as social enterprises or similar. IMUK therefore represents a sub-set of independent midwives, not all independent midwives.

89. During the consultation period IMUK argued strongly that the introduction of any form of external governance structure to their practice would run counter to their philosophy of woman-centred care and that IMs should

have complete freedom to deliver care in the way they see fit. Two main issues were raised:

a. A legal right to work – they argue that the new arrangements are denying them a human right to work if they can`t obtain appropriate and affordable indemnity cover by forcing them out of business.

b. A human right to make a choice of midwifery provision – they argue that women are being denied a right to choose thereby restricting women's choice in maternity services.

90. IMUK have met with officials and the Minister to discuss the issue. The solutions proposed by IMUK are chiefly based on the Government intervening either to underwrite individual midwives or to exempt them from the requirement to hold indemnity. The Department cannot allow an exemption as this goes against the founding principles of the UK legislation and the EU directive. Discussions to address their funding proposals are taking place, but this is a complex area and could tie the government into future funding if it were agreed. IMUK produced a business plan requesting the Government to intervene by either a government grant to inject capital into a new captive cell insurance scheme or, in respect of the scheme, the government to provide a guarantee to underwrite any loss over and above £100,000 of any one claim. We notified IMUK that we were unable to help due to concerns about fairness to other groups and the granting of state aid to the private sector.

91. It is the Department's view that independent midwives can now obtain affordable indemnity cover for the whole of the maternity care pathway either in the NHS or in the private sector. It does however; acknowledge that this is only achievable if they operate as part of some form of social enterprise or corporate entity, thus providing insurers with the requisite governance structures to allow them to obtain cover.

Estimating costs to independent midwives

92. It is difficult to quantify the cost impact of the proposed legislation on independent midwives due to:

- Limited information on the number of independent midwives as this number is suppressed in ONS data due to the small numbers practising. This is also a contributing factor to the issues around the cost of indemnity cover as it is difficult for the insurers to quantify the risk. This is being addressed separately with the ONS, but it will take a number of years for the data to be collected in such a way that will enable patterns in the data to be identified and fed through to the cost of indemnity cover. We have based our calculations on the information we have received from the NMC which says that in 2013-14, 154 NMC registrants declared their intention to practice as an independent midwife, but there is no data available on numbers actually practising.

- Limited data available on the caseloads of independent midwives. We have requested further information from independent midwifery organisations, but this has not been forthcoming in sufficient detail for us to draw any conclusions.
- The varying services provided. Not all of those midwives who declared an intention to practise independently will provide the full maternity pathway. Insurance is already available for midwives providing pre or post natal services and some independent midwives who provide only these services will be able to continue to practise unaffected.
- The different operating models that are being adopted to ensure compliance with the new legislation.

93. However, based on analysis of information that has been shared with us by some of the independent midwifery bodies, we estimate an annual cost of indemnity cover of around £15,000 per independent midwife per annum. Because of the difficulties noted above, we must emphasise that this figure is only a broad approximation. The number of clients, the number of births and the policy excess are all key factors in determining the cost of insurance or indemnity cover for an independent midwife.

94. If all of the 154 midwives identified by the NMC purchased indemnity cover at the rate established above, the total annual cost would be £2.310m. We consider this to be a maximum as fewer independent midwives may be practising in reality.

95. In addition there will be costs associated with establishing social enterprises. Information received indicates that this is likely to be in the region of £500k per organisation over two years. One such social enterprise has already been established and we are aware of a further two being considered. We expect that all midwives who wish to practise independently will be accommodated by up to one of these three organisations leading to final estimated costs of establishing social enterprises at £1.5m over two years.

EU v domestic elements of the proposal – additionally considerations

96. We have been unable to source any information on the number of cross-border patients who are likely to use the services of independent midwives (we have been unable to extrapolate from NHS figures because visitors and migrants are not identified separately, nor are users of midwifery services). However, the number will certainly be very low (given there are a maximum of 154 midwives seeing between, at most, 6 and 10 patients in total per year). The Association of British Insurers have advised us that the very small number of patients over which to spread the risk coupled with the potential for significantly costly events (which could be over £10m of lifetime costs as in the example quoted above) means that, *even with social enterprises in place*, it is unlikely that the

market would develop insurance products for independent midwives if just the EU elements of the proposal were implemented.

On the basis of this evidence, we have concluded that the costs to independent midwives would be no less if insurance were mandated for the EU elements alone. In fact, because of the difficult in estimating realistic premiums, insurance cover may not be available at all. In terms of incremental costs and benefits therefore, the domestic element extends the benefits significantly at little or no additional cost for independent midwives.

Costs to patients

97. In the consultation, a number of respondents said that the Order may impact on women who would have chosen to use the services of a specific independent midwife who is unable to obtain an affordable indemnity arrangement. Again the impact is difficult to quantify due to the lack of reliable information on the numbers of women giving birth with the assistance of independent midwives. However, we believe the impact will be small as:
    - Independent midwifery for the whole of the maternity care pathway will still be delivered by those independent midwives who have taken steps to ensure that they are able to obtain affordable indemnity arrangements, for example those who have engaged in a social enterprise.
    - Women will still be able to use independent midwives working as individuals for pre and post natal care as indemnity cover will be available for these services;
    - Women will be able to access NHS services free at the point of delivery for the full maternity pathway, or they will be able to pay via a private health care provider;
    - Women will benefit from receiving services that are appropriately indemnified.

98. As we say earlier it is expected that any additional costs these measures bring to individual health care professionals will be ultimately borne by patients.

Cost to Government

99. We do not expect these proposals to add any significant costs to Government. Some consultation responses suggested that there would be an increased cost to the NHS as pregnant women would no longer be able to use independent midwives. However, as we have made clear the Government's view is that independent midwives will still be able to practise in social enterprise groups. Whilst there may be a small number of increases in births in the NHS we would expect these costs to be marginal.

Costs to health care professional regulatory bodies

100. The obligation to have indemnity cover is set out in the legislation and is self-standing - however each health care professional regulatory body will develop its own approach to monitoring and enforcing the indemnity requirements. Therefore estimating the expected cost is problematic and the Impact Assessment cannot be definitive on implementation costs at this stage. The following cost calculations are provided on an indicative basis only.

101. The variety of potential approaches by the health care professional regulatory bodies to implementing these proposals is supported by the Research Report of the Independent Review Group which identified a range of costs for a number of different regulators as set out in the table below.

Table 8: Estimated transition cost of implementation of compliance monitoring by health care professional regulatory body

Regulatory body	Cost [1]
GMC	£370,000
HCPC	£300,000
NMC	£40,000
Total	**£710,000**

Notes:
1. Source: Independent review of the requirement to have insurance or indemnity as a condition of registration as a health care professional, 2010, Annex B Pricewaterhouse Coopers Report: *Professional insurance and indemnity for regulated health care professionals – policy review research* p 39 and information provided by GDC.

102. In response to the consultation regulators provided further information on their expected costs. The GOsC indicated that it did not envisage any additional costs arising from the Order with the GCC and the GOC indicating that whilst there would be some cost they expected it to be minimal. The GPhC also identified one-off costs associated with amending its rules, changing its systems and communicating the changes to registrants. The GPhC did not quantify these costs and given, the wide range of costs identified by Independent Review Group and the largely one-off nature of the costs identified we have not attempted to quantify these.

103. The HCPC, GMC and NMC all indicated that there would be some costs but that they expected them to be small, none of these organisations questioned the figures provided in the Impact Assessment and therefore we do not intend to make any changes to them.

104. In its consultation response, the GDC indicated that it expected the cost of implementation to be £85,000. Added to the figures identified by the Independent Review Group this makes a total estimated cost to the regulatory bodies of £795,000.

105. As the majority of costs identified will relate to implementation of the policy (e.g. changes to IT and communication to registrants) we have made the assumption that 10% of the costs identified (i.e. £80,000) will be related to the on-going administration of the process rather than the one-off costs of developing new systems and advertising changes to registrants and will be incurred annually. This is reflected in the assessment of overall costs of the scheme.

106. As the regulators are statutory bodies these costs do not represent a direct impact on business

107. Should these costs be passed on to the registrants, the range of additional costs varies considerably due to the size of the respective health care professional regulatory bodies.

Costs to employers

108. Costs may arise where individual professionals are required by their regulatory body to provide proof of employment and hence cover by some form of indemnity arrangement. Whilst it will be for the health care professional regulatory bodies to design their own system, it is anticipated that any burden this places on employers will be minimal and of negligible cost.

109. As part of the consultation, specific questions were asked with regard to costs and administrative burdens, however these did not result in any quantifiable costs being identified for employers and our view continues to be that these costs will be minimal.

110. As the Order does not place any requirements on employers any minimal costs that are placed on them will not constitute a direct impact.

Estimated benefits

Benefits to regulated health care professionals

111. Regulated health care professionals who are not already covered by an indemnity arrangement will benefit from the assurance that, should they be involved in a negligent act that causes harm, they would be covered by an appropriate indemnity arrangement. Furthermore they, as individuals, would not be financially liable and so would not be in danger of losing personal assets and, potentially, being made bankrupt. Bankruptcy may affect life chances (and so future income trajectory) and have stigma associated with it.

112. We believe that these benefits may be substantial but, because no data is routinely collected on the frequency and characteristics of these

events, which are in any case often settled out of court, we are unable to estimate the size of the benefits.

113. The presence of cover may well make the option of independent midwifery more attractive to potential clients as it will be clear that they have a route for redress and this may result in increased business.

114. The consultation further identified that the requirement would encourage membership of professional bodies: in turn this would ensure that health care professionals were better linked into the developments in their profession.

115. The GOsC also believed that the new legislation would enable it to change its current processes for monitoring indemnity provision which would result in reduced compliance costs for its registrants.

Benefits to the public and patients

116. It is primarily patients who bear the cost of adverse events, either in terms of costs or personal impact, and who would therefore benefit from the implementation of the policy.

117. Pricewaterhouse Coopers, which conducted the research for the Independent Review Group investigated several potential approaches to try and obtain relevant information to draw conclusions in this regard, but the absence of data made drawing robust conclusions impossible. As the research notes:

> 'Regulators capture data concerning the number of cases referred to them…We note that these are Fitness to Practise complaints and may not result in compensation claims being pursued…[W]e were not able to determine a "conversion rate" of complaints to claims for negligence, or the size of subsequent awards.'[10]

118. It further notes that:

> 'Claims within the NHS are covered by various clinical negligence risk pooling schemes. Whilst data is captured on all claim activity it is only held by speciality and not by profession. NHSLA data confirms that claims from obstetrics and gynaecology have the highest average cost. However, claims from surgery have the highest frequency, although no meaningful split of the professionals involved is captured….
>
> Claim frequency and severity data could not be extrapolated from an NHS environment to independent/private sector environment. This was due to NHS claims data not being captured by profession and no available robust data on the proportion of professional activity which

[10]Source: Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional, 2010, Annex B Pricewaterhouse Coopers Report: *Professional insurance and indemnity for regulated healthcare professionals – policy review research*, p 26

occurs inside and outside of a NHS environment. We understand that some private sector organisations may capture some of this information, but due to commercial sensitivity could not disclose this to us. In addition, we explored potential alternative sources of information (e.g. court data). However, there are no centralised readily accessible information sources on the frequency and severity of medical negligence claims through the court system.' [11]

119. The consultation responses also identified benefits to having a simplified consistent system which would provide further transparency and assurance for individuals seeking redress and close any existing gaps in cover.

Benefits to Government

120. For the tax payer, the benefits are those associated with cases where there is currently no recourse to redress. With the provision of cover, costs which might otherwise fall to the public purse can be met from an award pursuant to that award.

Benefits to health care professional regulatory bodies

121. By taking administrative procedures (e.g. refusing to grant or renew registration) rather than fitness to practise procedures, the health care professional regulatory bodies will be able to deal with issues around a lack of or insufficient indemnity arrangements both quickly and at considerably reduced expense (fitness to practise procedures can be lengthy and expensive requiring investigation, the collection of evidence, legal advice and hearings etc.).

Overall assessment of benefits

122. The lack of reliable data has made it impossible to produce specific monetised benefits. However we believe it is valid to assume that, with no transaction costs, premiums will equate to pay outs in the long run, which in turn is the cost of the damage done. The transaction cost, which will include administration costs and a fair return (in the main for the risk taken on by insurance companies), will be compensated for by the security offered to patients and the insured (who avoid being made bankrupt). We have therefore assumed that the annual monetised benefits are equal to the annual recurring cost to practitioners of taking out indemnity cover. We have assumed that these benefits will accrue to patients, though we believe there are significant benefits to health care professionals which we have been unable to estimate because of lack of data.

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[11] Source: Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional, 2010, Annex B Pricewaterhouse Coopers Report: *Professional insurance and indemnity for regulated healthcare professionals – policy review research*, p 31

OTHER IMPACTS

Insurance Providers

123. Insurance providers will receive the payments made by regulated health professionals for indemnity arrangements. This constitutes a direct impact on business which is equal to the costs to self-employed regulated health care professionals of acquiring indemnity arrangements.

SMALL AND MICRO BUSINESS ASSESSMENT

124. The cost impact of this policy will be to individual, self-employed contractors.

125. Whilst independent midwives operating as self-employed practitioners may be adversely affected where they are unable to secure cover, it is the intention of the domestic policy e that all health care professionals must have sufficient cover in place. The Department has worked extensively, over many years, with ndependent midwives to explore options in this area – these are described in paras 80-91. We have found (from independent research, discussions with insurance professionals and some groups of independent midwives themselves) that a social enterprise is the only realistic solution for obtaining affordable indemnity cover, and indeed some independent midwives are already successfully using that model.

EQUALITY

126. An Equality Analysis has been completed. It considers the potential impacts on each of the protected characteristics, and any steps we have taken to mitigate these. It concludes that the policy is proportionate and reasonable.

ANNEX A: Background information on estimating the number of health care professionals impacted by the policy

A1. The Independent Review Group commissioned bespoke research from Pricewaterhouse Coopers in which a relative risk indicator was developed to identify those professions operating predominantly within and outside of the NHS. The areas highlighted in red and amber in Table A1 are those which might be most likely to need an indemnity arrangement.

Table A1

Relative risk indication

Category of Healthcare professional	Number of registrants	Estimated proportion who work outside the NHS**
Registered with GMC	231,291	● (amber)
Registered with GDC	92,976	● (red)
Registered with NMC	665,704	● (amber)
Registered with GOC	23,319	● (red)
Registered with GOsC	4,187	● (red)
Registered with GCC	2,489	● (red)
(Previously) Registered with RPSGB	58,220	● (amber)
Registered with PSNI	2,200	● (amber)
Arts therapist	2,768	● (red)
Biomedical scientists	21,786	● (green)
Chiropodist/podiatrist	12,876	● (amber)
Clinical scientist	4,394	● (green)
Dietician	7,137	● (amber)
Occupational Therapist	30,127	● (green)
Operating Department Practitioner	10,048	● (amber)
Orthoptists	1,263	● (amber)
Paramedic	15,589	● (green)
Physiotherapist	44,734	● (amber)
Practitioner psychologists	15,244	● (amber)
Prosthetist / orthotist	865	● (amber)
Radiographer	26,319	● (amber)
Speech and language therapists	12,298	● (green)

*** ONS 4 quarter average July 2008 – June 2009 and from interviews with regulatory bodies, where available.*

Table key

Rating	Proportion working outside of NHS
● (green)	0 – 10%
● (amber)	10 – 75%
● (red)	75 – 100%

Source: Independent review of the requirement to have insurance or indemnity as a condition of registration as a health care professional, 2010, Annex B Pricewaterhouse Coopers

Report: Professional insurance and indemnity for regulated health care professionals – policy review research, p 32

A2. To identify how many individuals work in each of the professional groups within scope in the private sector we sourced data from the Office of National Statistics (ONS). The data, as set out in Table A2, indicates that, of the approximately 1.4 million health and social care professionals, there are around 25,000 self-employed individuals across the UK who are not currently required by statute or by their regulatory body guidance to hold an indemnity arrangement, excluding the ONS classification of "Therapists not elsewhere classified."

Table A2: Public and Private Employment Figures

Annual Population Survey (APS), Jan - Dec 2010 — Thousands, not seasonally adjusted

	UK						
	Private				Public		
2. PROFESSIONAL OCCUPATIONS	ALL	Employee	Self Employed		ALL	Employee	Self Employed
221. HEALTH PROFESSIONALS							
MEDICAL PRACTITIONERS	64	12	51		179	179	-
PSYCHOLOGISTS	6	1	5		24	24	-
PHARMACISTS & PHARMACOLOGISTS	29	19	10		13	13	-
OPHTHALMIC OPTICIANS	12	8	4		1	1	-
DENTAL PRACTITIONERS	26	1	25		9	9	-
SOCIAL WORKERS	21	15	6		98	98	*
3. ASSOCIATE PROFESSIONAL AND TECHNICAL							
321. HEALTH ASSOCIATE PROFESSIONALS							
NURSES	83	80	3		426	426	-
MIDWIVES	1	1	-		34	34	-
PARAMEDICS	*	*	-		21	21	-
MEDICAL RADIOGRAPHERS	4	4	-		20	20	-
CHIROPODISTS	6	-	6		5	5	-
DISPENSING OPTICIANS	6	5	1		-	-	-
PHARMACEUTICAL DISPENSERS	33	32	1		13	13	-
MEDICAL AND DENTAL TECHNICIANS	19	14	5		24	24	-
322. THERAPISTS							
PHYSIOTHERAPISTS	14	5	9		32	32	-
OCCUPATIONAL THERAPISTS	3	2	1		30	30	-
SPEECH AND LANGUAGE THERAPISTS	2	1	1		12	12	-
THERAPISTS NEC [1]	48	8	39		21	21	-
6. PERSONAL SERVICE OCCUPATIONS							
611. HEALTH CARE & RELATED PERSONAL SERVICES							
DENTAL NURSES	34	34	-		12	12	-
TOTAL	411	242	167		974	974	
TOTAL SELF EMPLOYED NOT REQUIRED TO HOLD INSURANCE/INDEMNITY EXCLUDING THERAPISTS NEC			25				

Source: Labour Market Survey

Footnotes:
- Estimates have been suppressed due to sample size. Small values are replaced by "*", zero estimates are shown with "-".
- Highlighted cells show groups not currently required to hold indemnity arrangements.

1 Classification of Therapists NEC includes chiropodists and osteopaths who are required by statute to hold indemnity. It also includes non regulated professionals, such as hydrotherapists and aromatherapists.

[2] Estimate of the total number of professionals not required by statute or code of conduct to hold insurance or indemnity.

A3. The ONS classification of "Therapists not elsewhere classified" includes Osteopaths and Chiropractors who are already required by statute to hold an indemnity arrangement. It also includes professions such as aromatherapists and hydrotherapists who are not statutorily regulated and who are not affected by the IA classification and are therefore excluded from this analysis.

A4. Accordingly, a table for those professional groups in scope has been produced (Table A3). This includes a line for "Therapists not elsewhere classified based on regulator data". This is based solely on data for

regulated health care professional therapists who are not currently required to hold an indemnity arrangement. This comprises data for Arts Therapists, Biomedical and Clinical Scientists, Dietitians, Orthoptists, Prosthetics and Orthotists, and Hearing Aid Dispensers using registrant data from the HCPC, the health care professional regulatory body responsible for these therapists, and identifies 12 thousand self-employed individuals.

Table A3 Public and Private Employment Figures Health care Professionals not currently required to hold an indemnity arrangement

	UK			
	Private			
Professional Group	**All**	**Employee**	**Self-Employed**	
Psychologists	6	1	5	
Nurses	83	80	3	
Chiropodists	6	0	6	
Physiotherapists	14	5	9	
Occupational Therapists	3	2	1	
Speech and Language Therapists	2	1	1	
Therapists NEC based on regulator data	15	2	12	
Total	129	91	37	
			37	

Therapists NEC based includes Arts Therapists, Biomedical and Clinical Scientists, Dietitians, Operating Department Practitioners, Orthoptists, Prosthetists and Orthotists, and Hearing Aid Dispensers, information from HCPC data.