

# Council meeting, 27 March 2013

Response to the Department of Health's Consultation on the Health Care and Associated Professions (Indemnity Arrangements) Order 2013

Executive summary and recommendations

### Introduction

In October 2012, the Council were provided with an update on the position in terms of introducing indemnity cover arrangements as a condition of registration. The Department of Health (England) began a consultation on proposals to introduce a requirement for healthcare professionals to have indemnity insurance on 22 February 2013. The Department is undertaking the consultation on behalf of all UK health administrations.

It is proposed that all healthcare professionals should be required to have professional indemnity insurance as a condition of registration with HCPC. This requirement could be met through an employer or by holding separate cover which could be secured through a professional body. Whilst the Department's proposals do not currently extend to social workers in England, there is a specific question within the consultation to seek views about whether the arrangement should be extended to social workers in England.

The Department of Health's consultation will run for twelve weeks and views are sought from stakeholders. HCPC will shortly begin drafting guidance for registrants explaining how this will affect them and also our plans on checking that indemnity arrangements are place, details of which will form the basis of further papers to be considered by Council.

### Decision

The Council is invited to discuss the attached paper and agree HCPC's response to the consultation as set out.

### **Background information**

18 October 2012, Council paper "Indemnity Cover Arrangements as a Condition of Registration."

# **Resource implications**

A project team has been established to oversee this project.

# **Financial implications**

Changes will need to be made to HCPC's registration and renewal forms and processes. Detailed costings are being worked up as part of the project initiation documentation.

**Appendices**Department of Health consultation paper (including the impact assessment and equality analysis).

# Date of paper 18 March 2013



# Response to the Department of Health's Consultation on the Health Care and Associated Professions (Indemnity Arrangements) Order 2013

The Health and Care Professions Council (HCPC) welcomes the opportunity to respond to this consultation.

The HCPC is the statutory regulator of the health, psychological and social care professionals governed by the Health and Social Work Professions Order 2001. We regulate the members of 16 professions. We maintain a register of professionals, set standards for entry to our register, approve education and training programmes for registration and deal with concerns where a professional may not be fit to practise. Our main role is to protect the health and wellbeing of those who use or need to use our registrants' services.

# **Consultation questions**

Q1. Do you agree that the requirement for healthcare professionals to have an indemnity arrangement in place should match the requirements set out in the Directive and place an obligation on health care professionals themselves to ensure that any indemnity arrangement in place is appropriate to their duties, scope of practise, and to the nature and extent of the risk? Please set out your reasons in your response.

Yes, we agree.

The obligation to ensure that any indemnity arrangement in place is appropriate to their duties, scope of practice, and to the nature and extent of the risk would rest upon the registrant concerned. We believe this is appropriate, as the registrant is the person best placed to make that assessment and it is consistent with the expectation, set out in our Standards of Proficiency, that registrants are "able to practise as an autonomous professional, exercising their own professional judgement."

Furthermore, an approach which requires registrants to ensure that their indemnity arrangements are appropriate is proportionate and avoids the imposition of any undue regulatory burden.

Q2. Do you agree with the proposed definition of an indemnity arrangement? Please set out your reasons in your response.

Yes, we agree with the proposed definition.

The proposed definition covers those circumstances where an individual has indemnity provided by their employer, where an individual has their own indemnity insurance in place, and any combination of the two.

- Q3. Do you agree with the proposed provisions that set out:-
  - (a) What information needs to be provided by healthcare professionals, and when, in relation to the indemnity arrangements they have in place;
  - (b) The requirement to inform the Regulator when cover ceases;
  - (c) The requirement for healthcare professionals to inform their regulatory body if their indemnity is one provided for by an employer?

Please set out your reasons in your response.

Yes, we agree with the proposed provisions.

We welcome the proposal which allows the regulators to make their own Rules, as this enables the regulators to introduce Rules which are appropriate for their own needs.

In order to implement these requirements, we will expect applicants and registrants to make declare at the point of registration, re-admission, renewal or restoration that they have or will have appropriate cover in place.

Q4. Do you agree with the proposal to allow healthcare professional regulatory bodies the ability to refuse to allow a healthcare professional to join, remain on, or return to, their register, or, for the GMC, to hold a license to practice unless they have an indemnity arrangement in place? Please set out your reasons in your response.

Yes, we agree.

This is consistent with the intention of the EU Directive.

Q5. Do you agree with the proposal to permit healthcare professional regulatory bodies to remove a healthcare professional from their register, withdraw their license to practice, or take fitness to practice action against them, in the event of there being an inadequate indemnity arrangement in place? Please set out your reasons in your response.

Yes, we agree.

As indemnity cover will be a mandatory requirement, the process for removing a person who does not have such cover should be a simple administrative step.

However, in some cases it may be more appropriate for failure to comply with the indemnity cover arrangements to be addressed via the Fitness to Practise process. This would apply where the failure to obtain or maintain appropriate cover was linked to some other misconduct. For example, a registrant who obtained insurance for the purpose of securing registration but then immediately cancelled it and practised without such cover in place. Misconduct of that nature should be addressed as a fitness to practise allegation.

Q6. Please provide any information with regard to the potential barriers to independent midwives moving to alternative governance and delivery practices in order to obtain appropriate indemnity arrangements.

We have no comment to make on this issue as the HCPC does not regulate midwives.

Q7. Do you agree that the provisions in the Draft Order should only apply to qualified healthcare professionals and not students? Please set out your reasons in your response.

We agree with this proposal.

Q8. Are there any equalities issues that would result from the implementation of the Draft Order which require consideration? If so, please provide evidence of the issue and the potential impact on people sharing the protected characteristics covered by the Equality Act 2010: disability, race; age; sex; gender reassignment; religion and belief; pregnancy and maternity and sexual orientation and carers (by association).

We do not have any equalities issues to raise.

Q9. Please provide comments as to the accuracy of the costs and benefits assessment of the proposed changes as set out in the Impact Assessment (including, if possible, the provision of data to support your comments).

As the impact assesment indicates, there is an absence of reliable data on this topic and consequently, we are unable to comment further.

Q10. Please provide information on the numbers of self-employed registered healthcare professionals and whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance.

HCPC does not hold this data.

Q11. Please provide information on the numbers of employed healthcare professionals who, in addition to working in an employed capacity covered by an employer's arrangement for indemnity or insurance, undertake self-employed practice. Where possible, please provide information as to whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance for that self-employed element of their practice.

HCPC does not hold this data.

Q12. Do you have any views or evidence as to the likely effect on costs or the administrative burden of the proposed changes set out in the Draft Order? Please provide information/examples in support of your comments.

Although the numbers of registrants likely to need to obtain additional indemnity cover is expected to be small, the requirements within the Draft Order will mean that changes will have to be made to our registration processes and the technology that supports these, and communicated to all registrants from the 15 professions affected. There will inevitably be a cost attached to these changes.

Q13. Do you think there are any benefits that are not already discussed relating to the proposed changes? Please provide information/examples in support of your comments.

No, we believe that the benefits associated with this Directive are clearly articulated throughout the consultation paper.

Q14. Do you have any further comments on the Draft Order itself?

We wish to see four minor amendments made to the Draft Order, as set out in the Annex to this submission.

Q15. What are your views on extending the requirement to hold an indemnity arrangement as a condition of registration to all professions statutorily

# regulated by the Health and Care Professions Council? This would cover Social Workers in England only.

If the policy view of Government is that arrangements similar to those provided for in the Directive should apply to social workers, we would have no objection in principle. However, the HCPC only regulates social workers in England. Such an arrangement would need to be achieved by a more comprehensive legislative proposal that applies to social workers throughout the UK.

The purpose of the Draft Order is to implement the Directive, the provisions of which are limited to health professionals. Seeking to widen the scope of the Draft Order would amount to 'gold plating' in the implementation of an EU law obligation.

### ANNEX

# Proposed Amendments to the Draft Health Care and Associated Professions (Indemnity Arrangements) Order 2013

1. In article 18 (which provides for the amendment of the Health Professions Council (Registration and Fees) Rules Order of Council 2003):

for "19 and 20" substitute "19 to 20".

**Explanatory Note:** This is simply a consequential amendment to give effect to the amendments that follow below.

2. After Article19 (amendment of rule 4) insert:

### "New rule 11B

**19A.** After rule 11A (continuing professional development) insert:

# "Indemnity arrangements

- **11B.** (1) Every registrant must comply with the requirements of Article 11A of the Order in respect of indemnity arrangements.
- (2) A registrant must promptly inform the Registrar if for any reason the registrant ceases to have in force an indemnity arrangement which provides appropriate cover.
- (3) The Registrar may at any time send a notice to a registrant requiring the registrant to submit:
  - (a) evidence that the registrant has an indemnity arrangement which provides appropriate cover; and
  - (b) such other information or evidence as the Registrar may reasonably require for the purpose of determining whether the registrant's indemnity arrangement does provide appropriate cover;

within such time period as the Registrar may specify in the notice, which shall be at least 7 days beginning with the day on which the notice was sent.

(4) If:

(a) having considered the evidence and information provided in response to a notice under paragraph (3), the Registrar is not satisfied that a registrant has in force an indemnity arrangement which provides appropriate cover; or

(b) a registrant fails to respond to such a notice within the period specified in the notice;

The Registrar may remove the name of the registrant from the register.

(5) This rule does not apply to a registrant in respect of registration as a social worker in England.".".

# Explanatory Note:

Article 14 of the Draft Order amends Article 11 of the Health and Social Work Professions Order to enable the HCPC to make rules to provide for registration to lapse where evidence of indemnity cover is not provided etc. As the Draft Order makes other consequential amendments to the HCPC rules, this amendment would introduce such a rule.

3. After new Article 19A (new rule 11B), insert:

### "Amendment of Schedule 1

**19B.** In Schedule 1 (application for admission to a part of the register), after paragraph (m), insert:

"(ma) Confirmation that there is in force in relation to the applicant, or will be as necessary for the purpose of complying with article 11A of the Order, appropriate cover under an indemnity arrangement"."

### Explanatory Note:

Schedule 1 to the Registration and Fees Rules provides for the content of the application form which must be completed when seeking admission to the register,. This amendment would require a specific confirmation of indemnity cover to be included within that form.

4. In Article 20 (amendment to Schedule 2):

for "evidence" substitute "confirmation".

# Explanatory Note:

Schedule 2 to the Registration and Fees Rules provides for the content of the application form which must be completed when seeking renewal of registration. As it is the content of a form, the reference to evidence of indemnity cover should be to confirmation of indemnity cover.



A paper for consultation

A UK WIDE CONSULTATION BY THE DEPARTMENT OF HEALTH ON BEHALF OF THE FOUR UK HEALTH DEPARTMENTS

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A paper for consultation

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# Contents

Contents	4
Executive summary	5
Introduction	7
Policy Background	7
Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare	
The Independent Review of the requirement to have insurance or indemnity as a condition registration as a healthcare professional	
Current Government Policy	11
Basis of this consultation	11
Scope and Impact of proposals	12
Content of the Draft Order	14
Questions for consultees on what we are proposing to introduce	14
Responding to this Consultation	21
Annexes	23
Annex A Regulatory Bodies, professions and Indemnity requirements	
Annex C Provisions of Draft Order relevant to specific regulators	
Annex D Consultation Questions	28

# Executive summary

This UK wide consultation issued on behalf of the four UK Health Departments, seeks comments and views on the draft Health Care and Associated Professions (Indemnity Arrangements) Order 2013 (the Draft Order). Section 60 Orders are subject to appropriate Parliamentary scrutiny through the affirmative resolution procedure. The requirement to consult is provided for in the Health Act 1999, in paragraph 9 of Schedule 3.

The Draft Order applies to the regulation of certain professions which have been devolved to Scotland. The Draft Order must therefore be laid before the Scottish Parliament as well as the Parliament in Westminster. While there is no legislative requirement for the Draft Order to be laid before either the Northern Ireland Assembly, or the National assembly for Wales, the policy proposals have the support of the Ministers in Northern Ireland and Wales and the outcome of the consultation will be reported to all UK health ministers.

Legislation in respect of the Pharmaceutical Society of Northern Ireland remains the responsibility of the Northern Ireland legislature and is subject to a separate consultation in Northern Ireland.

This Draft Order will implement Article 4(2)(d) of the European Union Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (the Directive). The Directive requires Member States to have systems of professional liability insurance or similar arrangements in place in relation to provision of cross border health care and places a requirement on Member States to ensure that, by 25 October 2013, they have transposed into domestic law:-

'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 [in Member States]'

In transposing the Directive the Government will also seek to implement the recommendations made by an Independent Review Group (chaired by Finlay Scott), 'Independent Review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional' (June 2010).

In its report, the Independent Review Group concluded that requiring healthcare professionals to have insurance or indemnity cover in place as a condition of their registration was the most cost effective and efficent means of achieving the policy objective that all registered healthcare professionals have indemnity cover to ensure that individuals harmed due to the negligent activities of healthcare professionals can seek redress through compensation.

The four UK Health Departments welcomed the findings of the Independent Review Group and accepted its conclusions and recommendations. In February 2011 the UK Government published the Command Paper 'Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers'. In this document, the Government confirmed its commitment to introduce requirements to require healthcare professionals to have insurance or indemnity cover in place as a condition of registration with their relevant regulatory body.

The Government intends to implement the requirements of the Directive and the recommendations of the Independent Review Group by requiring statutorily regulated healthcare professionals to hold insurance or indemnity cover as a condition of their registration. If a healthcare professional benefits from an indemnity arrangement as provided through their employer, this would be sufficient to meet the requirement for registration as a healthcare professional. If they provide services on a self employed basis, then they will have to comply with the requirements to have an indemnity arrangement in place as a condition of registration by arranging adequate cover themselves.

There are a number of other provisions of the Directive which have yet to be transposed into UK law and which will be consulted upon separately.

The healthcare professional regulatory bodies are independent statutory bodies whose role is to set and enforce standards of professional competence, conduct and ethics for individual healthcare professionals. The four UK Health Departments believe that it is unacceptable for individuals not to have access to recourse to compensation where they suffer harm through negligence on the part of a regulated healthcare professional. The previous administration began to implement a requirement for regulated healthcare professionals to have insurance or indemnity as a condition of registration as a means to achieve this policy goal. Implementation was paused after concerns were raised as to the manner of implementation. In response, the previous administration established an Independent Review Group to look at these issues.

This UK wide consultation paper sets out how the Government proposes to implement the requirements of the Directive in respect of individual registered healthcare professionals, whilst meeting the commitment to implement the recommendations of the Independent Review Group and the Command Paper. This is through the amendment of existing legislation and the introduction of new legislation.

The consultation will run for a period of 12 weeks, from 22 February 2013 to 17 May 2013. A series of questions are asked within this document, to which respondents are invited to reply by completing the accompanying consultation template.

# Introduction

# **Policy Background**

- 1. There is currently no consistency across the eight statutory healthcare professional regulatory bodies¹ falling within the remit of the UK Parliament, with regard to legislation or guidance on the need for individual regulated² healthcare professionals to hold insurance and indemnity cover. Legislation in respect of the Pharmaceutical Society of Northern Ireland is devolved to the Northern Ireland legislature and is the subject of a separate consultation in Northern Ireland.
- 2. Four of the healthcare professional regulatory bodies already have a statutory requirement for insurance or indemnity in place. Two others have legislation in place which has not yet been commenced, but do have guidance on the matter in their codes of conduct. Two of the healthcare professional regulatory bodies, the Nursing and Midwifery Council and the Health and Care Professions Council have no requirement in legislative provisions or in guidance, although the Nursing and Midwifery Council recommends its' registrants hold indemnity cover.
- 3. The four UK Health Departments are aware of concerns that have arisen about the fact that some healthcare professionals currently practise without cover, or insufficient cover and that in such circumstances those whom they treat may be left without means to seek redress in the event of a negative incident negligently caused by the activities of a healthcare professional(s). Individual tragedies caused by negligence should not be compounded by this.
- 4. The four UK Health Departments believe that it is unacceptable for individuals not to have access to recourse to compensation where they suffer harm through negligence on the part of a registered healthcare professional. The NHS Constitution in England reinforces this by including the 'right to compensation where you have been harmed by negligent treatment'. It should be noted that where an individual is employed, the employer can be liable for their acts or omissions, provided it can be shown that they took place in the course of their employment (vicarious liability).
- 5. There are different legislative provisions (some not in force) which place different obligations on healthcare professionals regarding the holding of insurance and indemnity cover. The previous administration sought to introduce requirements for all registered healthcare professionals. Concerns were raised about the proposed model of implementation of a requirement for healthcare professionals to have insurance and indemnity cover. In response, the previous administration commissioned an

- 7 -

<sup>&</sup>lt;sup>1</sup> Annex A of this consultation paper details the healthcare professional regulatory bodies and which groups of healthcare professionals they regulate, together with details of their requirements in relation to indemnity cover. <sup>2</sup> Regulation by Statute or Order in Council.

independent review of policy on insurance and indemnity cover for registered healthcare professionals.

6. At the same time, negotiations were ongoing in Europe on a Directive on patients' rights which raised, amongst other topics, the question of professional indemnity.

# <u>Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare</u>

7. On 28 February 2011, the European Union Commission, Parliament and European Council formally adopted 'Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare' (the Directive)<sup>3</sup>. This came into force on 9 March 2011. Article 4(2)(d) of the Directive places a requirement on Member States to ensure that, by 25 October 2013, they have transposed into domestic law:-

'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 [in Member States]'

8. Article 3 sets out the definitions for the purposes of the Directive:

Article 3(d) 'Member State of treatment' means the Member State on whose territory healthcare is actually provided to the patient.

Article 3(a) 'healthcare' 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;

Article 3(f) 'health professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or pharmacist within the meaning of Directive 2005/36/EC, or other professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a)of the Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment.

Article 3(g) 'Healthcare provider' means any natural or legal person or any entity legally providing healthcare on the territory of a Member State.

- 9. It is the Government's position therefore that the requirement within the proposed legislation will only apply to healthcare professionals who are registered and therefore regulated<sup>4</sup>. Corporate healthcare providers will either provide appropriate indemnity cover for the healthcare professionals that they employ or if that individual healthcare professional provides their services on a self employed basis, then they will have to comply with the requirements to have an indemnity arrangement in place as a condition of registration.
- 10. Additionally, Article 4 (2)(b) of the Directive requires Member States to ensure that:

<sup>&</sup>lt;sup>3</sup> <u>Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare</u>

<sup>&</sup>lt;sup>4</sup> By statute or Order in Council.

'healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options, on the availability, quality and safety of the healthcare they provide in the Member State of treatment and that they also provide clear invoices and clear information on prices, as well as on their authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States.'

11. Should the proposals that are subject to this consultation be implemented as planned, then this will contribute to delivering the requirements of Article 4(2)(b) by virtue of the fact that the healthcare professional regulatory bodies' registers are already published on-line for access and the fact of registration will confirm that a healthcare professional on a register will possess appropriate insurance or indemnity cover.

# The Independent Review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional

- 12. The specific purpose of the Review, which was commissioned before negotiations on the Directive had concluded was to make recommendations to Government as to whether requiring regulated healthcare professionals to have insurance or indemnity cover in place as a condition of their registration was the most cost effective and proportionate means of achieving the policy objective that registered healthcare professionals have indemnity cover to secure compensation where a healthcare professional has been negligent. An Independent Review Group (made up of representatives from the healthcare professional regulatory bodies, professional bodies, patient/public representatives and other interested parties) was established by the then Secretary of State for Health in England, with the support of Ministers in Northern Ireland, Scotland and Wales. The review group was led by Finlay Scott, the former Chief Executive of the General Medical Council.
- 13. 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 healthcare professionals; and
  - identify the practicalities of minimising associated costs to ensure that the impact is as proportionate as possible.
- 14. However, as set out in the Independent Review Group Report,

'it proved impossible to formulate conventional cost benefit analysis..... There was an almost complete absence of reliable data on the incidence and scale of failures to secure compensation because adequate assets were not available.'<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page 13

- 15. Pricewaterhouse Coopers also found that details of insurance and indemnity cover premiums are not widely available, due to its 'commercial in confidence' nature.
- 16. In light of this the Independent Review Group considered an alternative cost basis of:
  - a. Compliance the costs incurred by registrants in satisfying the requirement to have insurance or indemnity.
  - b. Compliance testing the costs incurred by regulators in determining whether registrants satisfy the requirement to have insurance or indemnity.
  - c. Enforcement the costs incurred by regulators when the requirement to have insurance or indemnity is not satisfied. <sup>6</sup>
- 17. The Independent Review Group reported in June 2010 and concluded that:'making insurance or indemnity a statutory condition of registration is the most cost effective
  and proportionate means of achieving the policy objective.'
- 18. It also made a number of recommendations on how the introduction of the requirement to hold indemnity or insurance cover might be implemented. These can be found at Annex B. The Independent Review Group concluded that such a requirement would best work as follows:
  - a. A statutory condition of registration would apply equally and unequivocally to all registered healthcare 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 healthcare 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.<sup>8</sup>

<sup>&</sup>lt;sup>6</sup> Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page14

<sup>&</sup>lt;sup>7</sup> 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

<sup>&</sup>lt;sup>8</sup> 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

19. In their formal response on 14 December 2010<sup>9</sup>, the four UK Health Departments accepted the recommendations of the Independent Review Group and undertook to introduce legislation to implement them at the next most appropriate opportunity.

# **Current Policy**

- 20. The Independent Review Group reported shortly after the General Election in May 2010. After consideration, the incoming Government and the Devolved Administrations welcomed the findings of the Independent Review Group and accepted its conclusions and recommendations.
- 21. Subsequently, the Government stated in its Command Paper *Enabling Excellence* (published in February 2011)<sup>10</sup> that:-

'The Coalition Government and the Devolved Administrations believe that the requirement that registrants should hold insurance or indemnity cover should be consistent across health regulation, and that introduction of any requirements should not be framed so as to require individual employees to obtain personal cover themselves when they are already covered by corporate or employer cover.'

- 22. Over and above these commitments, the Government must transpose into UK law the requirements of the Directive. Legislation to transpose the remainder of the Directive is being consulted upon separately.
- 23. The Scottish Government has recently completed a public consultation on the recommendations of the No-fault Compensation Review Group which was established in 2009. The 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 the scheme. The Review Group also recommended that the scheme should extend to all registered healthcare professionals in Scotland, not simply to those employed by NHS Scotland. The responses to the consultation are currently being considered.

# Basis of this consultation

24. After consideration of the need to implement the Directive and the work of the Independent Review Group the Government believes that it is right and proper to introduce provisions which require regulated healthcare professionals to have in place indemnity cover as a condition of registration. This consultation focuses on how this requirement might be implemented.

25. Existing provisions in law will be substituted with new provisions that will introduce a requirement for healthcare professionals to have in place appropriate indemnity cover as a condition of their registration. In relation to the two healthcare professional

<sup>&</sup>lt;sup>9</sup> Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response, DOH 2010

<sup>&</sup>lt;sup>0</sup> Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff DH 2011, p20

regulatory bodies <sup>11</sup> that currently have no provisions on indemnity cover, new provisions will be introduced. The legislative framework will impose the legal obligation to have indemnity cover on healthcare professionals but this will be supported by an enabling framework that gives the healthcare professional regulatory bodies the power to make rules setting out the processes and information they require in order to ensure that their healthcare professionals are covered by insurance or indemnity that is suitable for their purpose and which is appropriate for the nature and extent of the risk incurred in the practice of their profession.

26. By making appropriate amendments to the legislation of the healthcare professional regulatory bodies, the Government believes that this will deliver the implementation of the recommendations made by the Independent Review Group and ensure that the requirements of the Directive will have been met with regard to individual healthcare professionals. It should be emphasised that if a healthcare professional benefits from an indemnity arrangement as provided through their employer this would be sufficient to meet the requirement for registration as a healthcare 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.' 12

- 27. It should be noted though that this vicarious liability only extends to an individual's acts or omissions, provided it can be shown that they took place in the course of their employment.
- 28. This consultation does not address the issue of indemnity cover for corporate healthcare providers and provisions are not being made in respect of those individuals entered on or seeking entry to student registers where such registers are held by the healthcare professional regulatory bodies. Similarly no provisions are being made to require Social Workers regulated by the Health and Care Professions Council in England to hold indemnity as a condition of their registration. However, respondents are invited to provide their views on these matters as part of the consultation, in order to inform future policy development.

# Scope and Impact of proposals

29. There are some 1.4 million healthcare professionals on statutory registers. It will be for the individual healthcare professional regulatory bodies to determine how they will operate their newly acquired powers through rules and regulations.

<sup>&</sup>lt;sup>11</sup> Nursing and Midwifery Council and the Health and Care Professions Council

<sup>&</sup>lt;sup>12</sup> 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

- 30. As set out in the Impact Assessment accompanying this consultation, it is estimated that up to 59,000 self-employed healthcare professional registrants could potentially be affected by the introduction of a new statutory requirement to hold an indemnity arrangement. However, our analysis indicates that many healthcare professionals already hold a personal indemnity arrangement at the present time. We estimate that some 4,195 professionals will be affected by the requirement. Details on how this estimate was reached can be found in the accompanying Impact Assessment.
- 31. The Impact Assessment relating to these proposals has been drawn up using the best available data to make a series of assumptions. However, it should be emphasised that, in the reported absence of reliable data, there is a need to source further information, if available, and refine the data in order to test and validate the assumptions. Accordingly, the consultation asks a series of questions inviting respondents to provide information to test and validate the assumptions made in the Impact Assessment.

# Content of the Draft Order

# Questions for respondents on what we are proposing to introduce

- 32. The enabling legislation for each of the healthcare professional regulatory bodies is different. Therefore, delivery of the proposals will require amendments to each relevant piece of legislation. The attached draft Health Care and Associated Professions (Indemnity Arrangements) Order (the Draft Order) delivers these changes.
- 33. However, the intention of these proposals is to introduce consistent powers across all the healthcare professional regulatory bodies in respect of requirements relating to the need to possess insurance or indemnity cover as a condition of registration. The requirement to possess insurance or indemnity cover is defined as an 'indemnity arrangement' within the Draft Order and may comprise a policy of insurance, an arrangement made for the purposes of indemnifying a person, or a combination of the two.
- 34. Consequently, this consultation has been framed so that respondents can provide their views generally on the proposals, or in relation to the impact of them on specific health regulatory bodies or professions. The consultation response sheet that accompanies this consultation allows this detail to be indicated. Below is a description of each provision to assist respondents in understanding the reason and purpose behind the relevant underlying provisions in the Draft Order. Annex C allows respondents to isolate which parts of the Draft Order implement the provisions below for each Regulator.
- 35. **Provision 1**: Introduces a requirement for healthcare professionals to have an indemnity arrangement in place as required by Article 4(2)(d) of the Directive in order to be able to practise as a healthcare professional.
- 36. This provision mirrors the requirements of the Directive. In addition, it is framed in a manner that places the responsibility on healthcare professionals themselves to ensure that any indemnity arrangement in place is appropriate to their duties, scope of practice, and to the nature and the extent of the risks arising.
- 37. The four UK Health Departments' view is that, in keeping with wider professional responsibilities, the responsibility should be on healthcare professionals themselves (in conjunction with any insurance or indemnity provider and/or employer) to ensure that indemnity arrangements are appropriate to the nature and the extent of the risk that may be encountered in carrying out work in that profession. In common with the Independent Review Group, the four UK Health Departments believe that healthcare professionals and their insurers or indemnifiers are best placed to make this assessment. In addition, we also believe that it would be disproportionate to require the healthcare professional regulatory bodies to assess whether the individual indemnity arrangements of 1.4 million healthcare professionals were appropriate.

- 38. In the case of the legislative change for the General Medical Council, where possession of a licence to practise is required in order to treat patients as a doctor, the requirement to have an indemnity arrangement in place is a condition of holding such a licence.
  - Q1: Do you agree that the requirement for healthcare professionals to have an indemnity arrangement in place should match the requirements set out in the Directive and place an obligation on healthcare professionals themselves to ensure that any indemnity arrangement in place is appropriate to their duties, scope of practise, and to the nature and the extent of the risk? Please set out your reasons in your response.
- 39. **Provision 2**: Defines what an "Indemnity Arrangement" is, which may be an insurance policy, an arrangement for the purposes of indemnification, or a combination of both. This provision provides that either insurance or indemnity cover (or a combination) is sufficient to meet the relevant requirement to have an indemnity arrangement in place. As set out above, this ensures that cover via an employer's indemnity arrangement is sufficient to meet the requirement.
  - Q2: Do you agree with the proposed definition of an indemnity arrangement? Please set out your reasons in your response.
- 40. **Provision 3:** Provides healthcare professional regulatory bodies with a power to make rules on:
  - (a) What information needs to be provided by healthcare professionals, and when, to demonstrate that they have an indemnity arrangement in place in order to practise;
  - (b) Requirements for healthcare professionals to inform their regulatory body should cover under an indemnity arrangement cease; and,
  - (c) Requirements for healthcare professionals to inform their regulatory body if their indemnity arrangement is one provided by an employer;
- 41. These provisions allow regulators the power to make rules in relation to the nature of information they will require from healthcare professionals, the timing of when information is required, and the nature of the indemnity arrangement itself.
- 42. In the case of the legislative changes for the General Chiropractic Council and General Osteopathic Council, provisions may be made in rules in connection with the type of indemnity arrangement required. The four UK Health Departments believe that though there should be commonality in overall requirements upon healthcare professionals it should be for the healthcare professional regulatory bodies themselves to set out, in a manner that is appropriate to their business, how these should be delivered. In addition, the drafting provides that where a person is employed and so benefits from indemnity arrangements provided by their employer they would be able to rely on this to demonstrate that cover is in place. We have absolutely no intention of requiring healthcare professionals to obtain duplicate personal cover where employer cover is sufficient to meet risks. Further, it is recognised that some healthcare professionals may wish to rely on cover provided by employers but, at the time of registration, not have secured employment. The provisions permit regulators to make rules on what

- information they will require, and when, in these circumstances in order to permit registration.
- 43. Finally, it is recognised that there will be cases where individuals will seek registration as a healthcare professional and seek to work in an employed environment, and so enjoy the benefit of an indemnity arrangement provided by their employer. Employers recruiting to such roles would most likely seek to only employ those people already registered with a Regulator. Therefore, if registration was linked to possession of an indemnity arrangement this could have the effect of creating additional burdens for the individual (that is, an individual may have been required to take out personal cover for the sole purpose of registration, before then acquiring the benefit of an employer's cover after taking up a job). To avoid this unintended consequence of the policy, the Draft Order provides that regulators can request information about what indemnity arrangement will be in place by the time an individual commences practice. We believe it is correct that the healthcare professional regulatory bodies should have the freedom to make rules on what safeguards need to be in place to ensure compliance with the requirement to have cover in place in order to practise.
  - Q3: Do you agree with the proposed provisions that set out:
  - (a) What information needs to be provided by healthcare professionals, and when, in relation to the indemnity arrangement they have in place;
  - (b) The requirement to inform the Regulator when cover ceases; and,
  - (c) The requirement for healthcare professionals to inform their regulatory body if their indemnity arrangement is one provided by an employer?

Please set out your reasons in your response.

- 44. **Provision 4**: Gives healthcare professional regulatory bodies the ability to refuse to allow a healthcare professional to join, remain on, or return to, their register in certain circumstances.
- 45. These provisions give force to the requirement that healthcare professionals must have an indemnity arrangement in place. Should they not, then these provisions permit the healthcare professional regulatory bodies to make appropriate decisions that will have consequences for a healthcare professional's registration, or, in the case of the GMC, their licence to practise. The registration requirements across the healthcare professional regulatory bodies differ but, in basic terms, the provisions allow them to refuse to allow a healthcare professional to join, remain on, or return to a healthcare professional regulatory body register unless they have an indemnity arrangement in place.
  - Q4: Do you agree with the proposal to allow healthcare professional regulatory bodies the ability to refuse to allow a healthcare professional to join, remain on, or return to, their register, or, for the GMC, to hold a licence to practise unless they have an indemnity arrangement in place? Please set out your reasons in your response.

- 46. **Provision 5:** Permits healthcare professional regulatory bodies to either administratively remove a healthcare professional from their register, withdraw their licence to practise, or take fitness to practise action against them, in the event of there not being an indemnity arrangement in place.
- 47. Fitness to practise action is a key duty of all of the healthcare professional regulatory bodies. As evidenced by the annual reports and accounts of these bodies it is an expensive process, which can take several months to resolve from start to finish. We believe that, in most cases, should a professional be unable to demonstrate that they have an indemnity arrangement in place, then the regulator should be able to take swifter and more proportionate administrative action to remove them from their register or withdraw their licence to practise, and so remove their ability to practise, without the need to handle the case through their fitness to practise procedures.
- 48. However, it is also recognised that there are some circumstances in which it might be appropriate to take fitness to practise action against a healthcare professional who does not comply with these requirements. Non-exhaustive examples of when this might be appropriate could be (i) a healthcare professional having an indemnity arrangement in place which is inappropriate to the scale of risk caused by their practice, or, (ii) a healthcare professional taking out an indemnity arrangement for the purpose of securing registration but then subsequently cancelling it and practising without such an arrangement being in place. In circumstances such as these, we believe it is right that the healthcare professional regulatory bodies should have the power to decide whether such activity brings into question the fitness to practise of the healthcare professionals they regulate and, if they feel it does, take action appropriately.

Q5: Do you agree with the proposal to permit healthcare professional regulatory bodies to remove a healthcare professional from their register, withdraw their license to practise, or take fitness to practise action against them, in the event of there being an inadequate indemnity arrangement in place? Please set out your reasons in your response.

# Transitional and saving provisions

49. Schedule 3 to the draft Order makes transitional and saving provisions, which allow indemnity arrangements/ insurance cover to continue in force for the transitional period, provided that the indemnity arrangement was commenced on or before the 24 October 2013. The transitional period is the twelve month period that ends on the 24 October 2014. The indemnity arrangement must be adequate and appropriate, and any rules made under previous provisions will be saved to the extent that the transitional arrangements apply. The Registrar must request written evidence that the healthcare professional has taken out cover in accordance with this provision.

## Wider Consultation Questions

# Independent Midwives

- 50. The inability of independent midwives to obtain commercial cover has been an ongoing concern. For 2011-12, 170 individuals across the UK declared to the NMC their intention to practise as independent midwives<sup>13</sup>. Whilst these individuals have historically been unable to obtain individual indemnity or insurance cover, independent research<sup>14</sup>, commissioned by the Nursing and Midwifery Council and Royal College of Midwives has suggested that independent midwives would be able to obtain insurance as employees within a corporate structure.
- 51. We know this model of maternity care delivery is viable because midwives operating such models have been able to purchase insurance for the whole of the midwifery care pathway and are delivering maternity services, both inside and outside the National Health Service. It is understood that this model is being explored with a view to encompassing the majority of independent midwives. Furthermore, the Department of Health in England is currently reviewing NHS indemnity arrangements with regards to opening up the Clinical Negligence Scheme for Trusts (CNST) to non-NHS bodies delivering NHS care.
- 52. Accordingly, given the small scale of the professional group, the assumption made for the purposes of the Impact Assessment is that the majority of independent midwives will be able to obtain cover via one of the routes set out above, although it may require such midwives to change the governance framework for their care and their delivery practices to comply with an indemnity policy.

Q6: Please provide any information with regard to the potential barriers to independent midwives moving to alternative governance and delivery practices in order to obtain appropriate indemnity arrangements.

### Students

53. It is the four UK Health Department's belief that, where they are registered by the healthcare professional regulatory bodies, students should be omitted from the requirement to have in place an indemnity arrangement. For instance, the General Optical Council have a specific student register. Optical students can come into contact with patients, the public, and service users as part of their training. However, the activities of students would be covered by indemnity arrangements in place relating to the environment in which they are undertaking training, or those who supervise them. In addition, whilst students are training to become healthcare professionals, they are not formally considered to be healthcare professionals. Therefore, the requirements within the Directive would not apply to them and consequently, the Department does not propose to extend these requirements to students.

<sup>13</sup> Local Supervising Authority data, NMC 2012

<sup>&</sup>lt;sup>14</sup> Flaxman Partners: *The Feasibility and Insurability of Independent Midwifery in England* 2011

Q7: Do you agree that the provisions in the Draft order should only apply to qualified healthcare professionals and not students? Please set out your reasons in your response.

# Equality impacts of proposals

- 54. The four UK Health Departments and the healthcare professional regulatory bodies are covered by the Public Sector Equality Duty in the Equality Act 2010, in respect of their public functions. The new Duty covers the following protected characteristics: age; disability; gender reassignment; pregnancy and maternity; race (includes ethnic or national origins, colour or nationality); religion or belief (includes lack of belief); sex and sexual orientation. There are three parts to the Duty and public bodies must, in exercising their functions, have due regard to all of them. They are:
  - o The need to eliminate unlawful discrimination, harassment and victimisation;
  - Advance equality of opportunity between people who share a protected characteristic and people who do not; and,
  - Promote good relations between people who share a protected characteristic and those who do not.
- 55. We have considered equalities issues whilst producing the Draft Order and our initial screening suggests that the proposed changes will not have any significant impact on any of the equalities strands. You can find our equality analysis in the Impact Assessment that accompanies this Draft Order.
  - Q8: Are there any equalities issues that would result from the implementation of the Draft Order which require consideration? If so, please provide evidence of the issue and the potential impact on people sharing the protected characteristics covered by the Equality Act 2010: disability; race; age; sex; gender reassignment; religion & belief; pregnancy and maternity and sexual orientation and carers (by association).

## Costs and benefits

- 56. The Impact Assessment has been drawn up using the best available data to make a series of assumptions on the costs and benefits of the proposed legislation. However, it should be emphasised that, in the reported absence of reliable data, there is a need to source further data, if available, and refine the data in order to test and validate the assumptions.
  - Q9: Please provide comments as to the accuracy of the costs and benefits assessment of the proposed changes as set out in the Impact Assessment (including, if possible, the provision of data to support your comments).
  - Q10: Please provide information on the numbers of self employed registered healthcare professionals and whether they are in possession of indemnity cover

or business insurance which includes public liability insurance and professional indemnity insurance.

Q11: Please provide information on the numbers of employed healthcare professionals who, in addition to working in an employed capacity covered by an employer's arrangement for indemnity or insurance, also undertake self-employed practice. Where possible, please provide information as to whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance for that self -employed element of their practice.

Q12: Do you have views or evidence as to the likely effect on costs or the administrative burden of the proposed changes set out in the Draft Order? Please provide information/examples in support of your comments.

Q13: Do you think there are any benefits that are not already discussed relating to the proposed changes?

Please provide information/examples in support of your comments.

Q14: Do you have any further comments on the Draft Order itself?

# **Supplementary questions**

Social Workers

57. The terms of reference of the Independent Review Group, and the provisions in the Directive, only apply to healthcare professionals. As such, despite the fact that following the Health and Social Care Act 2012, social workers in England are regulated by the Health and Care Professions Council, provisions in the draft Order do not apply to social workers. The Department of Health in England would seek to use this consultation to evaluate views as to whether this exclusion should be maintained.

Q15: What are your views on extending the requirement to hold an indemnity arrangement as a condition of registration to all professionals statutorily regulated by the Health and Care Professions Council? This would cover Social Workers in England only.

58. A complete list of these consultation questions is reproduced at Annex D and on the consultation response document published with the Draft Order.

# Responding to this Consultation

### Consultation Process

- 1 This document launches a twelve week consultation on amendments to the legislation regarding registration requirements for the regulatory bodies.
- 2 The consultation is being run, as far as is practical, in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). The closing date for the consultation is **17 May 2013.**
- 3 There is a full list of the questions we are asking in this consultation at Annex D and there is a consultation response document on the Department's website which can be printed and sent by post to: Healthcare Professions Indemnity Consultation, 2N12 Quarry House, Quarry Hill, Leeds LS2 7UE
- 4 Alternatively, comments can be sent by e-mail to: <a href="https://www.hrdlistening@dh.gsi.gov.uk">hrdlistening@dh.gsi.gov.uk</a>
- 5 You may also complete the online consultation response document at <a href="http://consultations.dh.gov.uk">http://consultations.dh.gov.uk</a>
- 6 It will help us to analyse the responses if respondents fill in the consultation response document but responses that do not follow the structure of the questionnaire will be considered equally. It would also help if responses were sent in Word format, rather than pdf.

## Criteria for consultation

- 7 This consultation follows the Government Code of Practice, in particular we aim to:
  - Formally consult at a stage where there is scope to influence the policy outcome;
  - Consult for a sufficient period;
  - Be clear about the consultation process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
  - Ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
  - Keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees 'buy-in' to the process;
  - Analyse responses carefully and give clear feedback to participants following the consultation; and,
  - Ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.
- 8 The full text of the code of practice is on the Better Regulation website at: www.bis.gov.uk/policies/better-regulation/consultation-guidance

# Comments on the consultation process itself

9 If you have any concerns or comments which you would like to make relating specifically to the consultation process itself please contact

Consultations Coordinator, Department of Health 3E48, Quarry House Quarry Hill Leeds LS2 7UE

10 Please do not send consultation responses to this address.

# **Confidentiality of information**

- 11 We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter: <a href="https://www.dh.gov.uk/en/FreedomOfInformation/DH\_088010">www.dh.gov.uk/en/FreedomOfInformation/DH\_088010</a>
- 12 Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).
- 13 If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.
- 14 The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

# Summary of the consultation responses

15 A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the DH website (www.dh.gov.uk).

# **Annexes**

# **Annex A Regulatory Bodies, professions and Indemnity requirements**

Regulatory Bodies	Professions	No. of	Professions under the regulatory body	Indemnity Requirements
	regulated	Registrants		
General Chiropractic Council	1	2,700	Chiropractors	Required for registration by statute
General Dental Council	7	99,518	Dentists	In Guidance. Failure to hold
			Clinical Dental Technicians	indemnity leads to Fitness to
			Dental Hygienists	Practise proceedings
			Dental Nurses	
			Dental Technicians	
			Dental Therapists	
			Orthodontic Therapists	
General Medical Council	1	246,075	Doctors	In Guidance. Failure to hold
				indemnity leads to Fitness to
				Practise proceedings
General Optical Council	2	23,935	Optometrists	Required for registration by statute
			Dispensing Opticians (including student Opticians,	(not for student or businesses)
			student Optometrists and Optical businesses)	
General Osteopathic Council	1	4,585	Osteopaths	Required for registration by statute
General Pharmaceutical Council	2		Pharmacists	In Guidance. Failure to hold
		12,772	Pharmacy technicians	indemnity leads to Fitness to
		·		Practise proceedings
Health Professions Council	15	3,127	Arts therapists	No Guidance
		,	Biomedical Scientists	
			Chiropodists/podiatrists	1
			Clinical Scientists	1
		7,789	Dietitians	1
		1,724	Hearing aid dispensers	1
		31,928	Occupational therapists	1
			Operating department practitioners	1
		1,286	Orthoptists	1
		17,935	Paramedics	
		46,479	Physiotherapists	1
			Prosthetists/orthotists	1
		26,533	Radiographers	1
		13,175	Speech and Language therapists	1
			Practitioner psychologists	1
Nursing and Midwifery Council	2	627,535		Recommended under Code of
		44,560	Midwives	Conduct
Pharmaceutical Society of Northern	1	2,098	Pharmacists in Northern Ireland	In Guidance. Failure to hold
Ireland				indemnity leads to Fitness to
				Practise proceedings

Source: Regulatory Body registration data

Annex B Recommendations of the 'Independent Review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional"

**Recommendation 1:** There should be a statutory duty upon registrants to have insurance or indemnity in respect of liabilities which may be incurred in carrying out work as a registered healthcare professional.

**Recommendation 2:** In relation to the condition of registration, the roles of healthcare professional regulators should be supported by powers not duties; and those powers should include:

- a. A power to require relevant information to be provided to the Registrar in order to determine whether a registrant, or applicant for registration, has cover.
- b. A power to require registrants to inform the Registrar if cover ceases.
- c. A power to refuse to grant registration to an applicant who fails to comply with a request for information or fails to demonstrate that they have, or will have, cover.
- d. A power to withdraw registration from a registrant who fails to comply with a request for information or fails to demonstrate that they have, or will have, cover.
- e. A power to refer a registrant into fitness to practise procedures if the cover is alleged to be inadequate or inappropriate to the registrant's practice.

**Recommendation 3:** Relevant legislation should be harmonised across healthcare professional regulators, with common duties on registrants and common powers for healthcare professional regulators.

**Recommendation 4:** There should be a review of existing legislation, including that in force for the General Chiropractic Council, General Optical Council and General Osteopathic Council.

**Recommendation 5:** Within a harmonised framework, it should be for each healthcare professional regulator to decide, using a risk based approach, how best to exercise its powers.

**Recommendation 6:** Healthcare professional regulators should cooperate with system regulators, primary care organisations, and the independent sector to maximise coordination and minimise duplication.

**Recommendation 7:** Healthcare professional regulators should work with employers, trade unions and other representative bodies, and defence organisations to communicate to registrants the importance of insurance or indemnity and to explain how the condition of registration can be satisfied.

**Recommendation 8**: Healthcare professional regulators should explore, for example through pilot studies, how best to introduce the statutory condition of registration in a way that secures registrants' support and compliance rather than resistance.

**Recommendation 9:** Healthcare professional regulators should be given adequate time to prepare but Ministers should set a target date by which the statutory condition of registration has been implemented for all registrants.

**Recommendation 10:** To maintain and enhance public confidence, the Council for Healthcare Regulatory Excellence should report on each healthcare professional regulator's use of the relevant powers, as part of its annual performance review.

**Recommendation 11:** In consultation with insurers and indemnifiers, healthcare professional regulators should consider the case for communicating to patients, clients and the public, for example through regulators' websites, the value of insurance and indemnity, when they can assume it is in place, when they may need to check and how they would do so.

**Recommendation 12:** For the minimisation of doubt, the legislation should ensure, and make clear, that healthcare professional regulators are not liable for a breach of duty by a registrant provided that the regulator has acted reasonably.

**Recommendation 13:** In relation to personal cover required for self-employed practice, there should be a duty upon registrants to provide full disclosure of relevant facts to their insurer or indemnifier.

**Recommendation 14:** When personal cover for self-employed practice is alleged by a healthcare professional regulator to be inadequate or inappropriate, enforcement action should be through fitness to practise procedures, not administrative procedures.

**Recommendation 15:** Provided that there has been full disclosure of relevant facts, in the event that personal cover for self-employed practice is alleged to be inadequate or inappropriate, registrants should be entitled to rely on the defence that they have acted in accordance with the proposals of their insurer or indemnifier.

**Recommendation 16:** Healthcare professional regulators should make clear that, if registrants wish to change the scope of their practice, they should first have, or acquire, adequate and appropriate insurance or indemnity.

**Recommendation 17:** In relation to self-employed practice, healthcare professional regulators should consider their requirements for run-off cover and how to deal with past periods when the statutory condition of registration had been breached.

**Recommendation 18**: Healthcare professional regulators should explain to registrants that Good Samaritan acts fall outside the requirement to have insurance or indemnity as a condition of registration; and should provide guidance to registrants on good neighbour acts.

**Recommendation 19:** When implementing the condition of registration, healthcare professional regulators should seek to ensure, as far as they can, that they do not inadvertently jeopardise the availability of personal cover through membership related schemes provided by trade unions and others.

**Recommendation 20**: In relation to groups for whom the market does not provide affordable insurance or indemnity, the four health departments should consider whether it is necessary to enable the continued availability of the services provided by those groups; and, if so, the health departments should seek to facilitate a solution.

# **Annex C Provisions of Draft Order relevant to specific regulators**

Regulatory Body	Order, Schedule 1 Relevant Clause
General Chiropractic Council	Part 5 Provision 1 Para. 10"37(1)" Provision 2 Para. 10 "37(2-3)" Provision 3 Para. 10 "37(4-7)" Provision 4 Para. 10 "37(8)" Provision 5 Para. 10 "37(9)"
General Dental Council	Part 2 Provision 1 Para. 4 "26A(1)" and Para. 5 "36L(1)" Provision 2 Para. 4 "26A(2-3)" and Para. 5 "36L(2-3)" Provision 3 Para. 3 "18(C)(2)" Para. 4 "26A(4-7)" and Para. 5 "36L(4-7)" Provision 4 Para. 4 "26A(8)(a-b)" and "26A(10)" Para. 5 "36L(8)(a-b)" "36L(10)" and Para. 6 Provision 5 Para. 4 "26A(8)(c)" and "(9)" and Para. 5 "36L(8)(c)" and "(9)"
General Medical Council	Part 1 Provision 1 Para. 1 "44c (1)" Provision 2 Para. 1 "44c (2-3)" Provision 3 Para. 1 "44c (4-7)" Provision 4 Para. 1 "44c (8)" and Para 1 (2) Provision 5 Para. 1 "44c (9)"
General Optical Council	Part 3 Provision 1 Para. 7 "10A(1)" Provision 2 Para. 7 "10A(2-3)" Provision 3 Para. 7 "10A(4-7)" and Para. 8 Provision 4 Para. 7 "10A(8)(a-b)" and "10A(10)" Provision 5 Para. 7 "10A(8)(c)" and "10A(9)"
General Osteopathic Council	Part 4 Provision 1 Para. 9 "37(1)" Provision 2 Para. 9 "37(2-3)" Provision 3 Para. 9 "37(4-7)" Provision 4 Para. 9 "37(8)" Provision 5 Para. 9 "37(9)"
General Pharmaceutical Council	Part 8 Provision 1 Para. 35 "32(1)" Provision 2 Para. 35 "32(2-3)" Provision 3 Para 34, Para. 35 "32(4-7)" Provision 4 Para. 35 "32(8)" "32(10)(a)"and Para. 37-39 Provision 5 Para. 35 "32(9)" and "32(10)(b)"
Health and Care Professions Council	Part 6 Provision 1 Para. 15 "11A(1)" Provision 2 Para. 15 "11A(2-3)" Provision 3 Para. 15 "11A(4-6)" Provision 4 Para. 12- 14 Para. 15 "11A(8), Para. 16-20 Provision 5 Para. 15 "11A(7)"and "11A(9)"
Nursing and Midwifery Council	Part 7 Provision 1 Para. 25 "12A(1)" Provision 2 Para. 25 "12A(2-3)" Provision 3 Para. 25 "12A(4-6)" Provision 4 Para. 22 to 24, Para. 25 "12A(8)" Para. 26-32 Provision 5 Para. 25 "12A(7)" and "12A(9)"
Pharmaceutical Society of Northern Ireland	Legislation devolved to Northern Ireland Assembly

## **Annex D Consultation Questions**

Q1: Do you agree that the requirement for healthcare professionals to have an indemnity arrangement in place should match the requirements set out in the Directive and place an obligation on healthcare professionals themselves to ensure that any indemnity arrangement in place is appropriate to their duties, scope of practise, and to the nature and the extent of the risk? Please set out your reasons in your response.

Q2: Do you agree with the proposed definition of an indemnity arrangement? Please set out your reasons in your response.

Q3: Do you agree with the proposed provisions that set out:

- (a) What information needs to be provided by healthcare professionals, and when, in relation to the indemnity arrangement they have in place;
- (b) The requirement to inform the Regulator when cover ceases; and,
- (c) The requirement for healthcare professionals to inform their regulatory body if their indemnity arrangement is one provided by an employer?

Please set out your reasons in your response.

Q4: Do you agree with the proposal to allow healthcare professional regulatory bodies the ability to refuse to allow a healthcare professional to join, remain on, or return to, their register, or, for the GMC, to hold a licence to practise unless they have an indemnity arrangement in place? Please set out your reasons in your response.

Q5: Do you agree with the proposal to permit healthcare professional regulatory bodies to remove a healthcare professional from their register, withdraw their license to practise, or take fitness to practise action against them, in the event of there being an inadequate indemnity arrangement in place? Please set out your reasons in your response.

Q6: Please provide any information with regard to the potential barriers to independent midwives moving to alternative governance and delivery practices in order to obtain appropriate indemnity arrangements.

Q7: Do you agree that the provisions in the Draft order should only apply to qualified healthcare professionals and not students? Please set out your reasons in your response.

Q8: Are there any equalities issues that would result from the implementation of the Draft Order which require consideration? If so, please provide evidence of the issue and the potential impact on people sharing the protected characteristics covered by the Equality Act 2010: disability; race; age; sex; gender reassignment;

religion & belief; pregnancy and maternity and sexual orientation and carers (by association).

Q9: Please provide comments as to the accuracy of the costs and benefits assessment of the proposed changes as set out in the Impact Assessment (including, if possible, the provision of data to support your comments).

Q10: Please provide information on the numbers of self employed registered healthcare professionals and whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance.

Q11: Please provide information on the numbers of employed healthcare professionals who, in addition to working in an employed capacity covered by an employer's arrangement for indemnity or insurance, undertake self-employed practice. Where possible, please provide information as to whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance for that self -employed element of their practice.

Q12: Do you have views or evidence as to the likely effect on costs or the administrative burden of the proposed changes set out in the Draft Order? Please provide information/examples in support of your comments.

Q13: Do you think there are any benefits that are not already discussed relating to the proposed changes?

Please provide information/examples in support of your comments.

Q14: Do you have any further comments on the Draft Order itself?

Q15: What are your views on extending the requirement to hold an indemnity arrangement as a condition of registration to all professionals statutorily regulated by the Health and Care Professions Council? This would cover Social Workers in England only.

Draft Order in Council laid before Parliament and the Scottish Parliament under section 62(10) of the Health Act 1999, for approval by resolution of each House of Parliament and the Scottish Parliament.

## DRAFT STATUTORY INSTRUMENTS

## 2013 No.

## HEALTH CARE AND ASSOCIATED PROFESSIONS

# Health Care and Associated Professions (Indemnity Arrangements) Order 2013

Made - - - - 2013

Coming into force in accordance with article 1(2) and (3)

At the Court at Buckingham Palace, the xx day xx of xx 2013

Present,

The Queen's Most Excellent Majesty in Council

This Order in Council is made in exercise of the powers conferred by sections 60 and 62 of, and Schedule 3 to, the Health Act 1999(a).

The Secretary of State and the Scottish Ministers published a draft Order and invited representations as required by paragraph 9(1) and (3) of Schedule 3 to that Act.

The period of three months mentioned in paragraph 9(4) of that Schedule expired before a draft of this Order was laid before Parliament and the Scottish Parliament.

A draft of this Order in Council has been approved by resolution of each House of Parliament and the Scottish Parliament, in accordance with section 62(10) of that Act.

Accordingly, Her Majesty is pleased, by and with the advice of her Privy Council, to make the following Order in Council.

<sup>(</sup>a) 1999 c. 8. Section 60 has been amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act"), section 26(9); the Health and Social Care Act 2008 (c. 14) ("the 2008 Act"), Schedule 8, paragraph 1, and Schedule 10, paragraph 10; sections 209 and 210 of the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"); and S.I. 2002/253 and 254. Section 62 has been amended by: the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 194 and 197, and Schedule 4; and the 2008 Act, Schedule 8, paragraph 2, and Schedule 10, paragraph 11. Schedule 3 has been amended by: the 2002 Act, section 26(10); the Health and Social Care (Community Health and Standards) Act 2003 (c. 43), Schedule 11, paragraph 67, and Schedule 14, Part 4; the Health Act 2006 (c. 28), section 33 and Schedule 9; the 2008 Act, Schedule 8, paragraphs 3 to 10 (although paragraph 10 is not yet in force); the 2012 Act, section 211 and S.I. 2002/254.

#### Citation and commencement

- **1.**—(1) This Order may be cited as the Health Care and Associated Professions (Indemnity Arrangements) Order 2013.
  - (2) This article comes into force on the day after the day on which this Order is made.
  - (3) Article 2 and article 3 come into force on [date].
- (4) Where this Order amends other legislation and makes transitional provisions in relation to those amendments, those amendments and transitional provisions have the same extent as the legislation being amended.

#### Amendments

- **2.**—(1) Schedule 1 (amendments to legislation regulating health care and associated professions) has effect.
  - (2) Schedule 2 (other amendments of subordinate legislation) has effect.

## Transitional, transitory or savings provisions

- **3.**—(1) The transitional and saving provisions set out in Schedule 3 have effect.
- (2) In connection with the commencement of any provision of this Order, the Privy Council may by order make such transitional, transitory or saving provisions as it considers appropriate.
  - (3) The power to make an order under paragraph (2) may be exercised—
    - (a) so as to make different provision—
      - (i) with respect to different cases or different classes of cases, or
      - (ii) in respect of the same case or class of case for different purposes;
    - (b) in relation to all cases to which the power extends or in relation to all those cases subject to specified exceptions; or
    - (c) so as to make any supplementary, incidental or consequential provisions which the Privy Council considers necessary or expedient.
- (4) The power of the Privy Council to make an order under paragraph (2) may be exercised by any two or more members of the Privy Council.
- (5) The making of an order under paragraph (2) shall be sufficiently signified by an instrument signed by the Clerk to the Privy Council.
- (6) The power to make an order under paragraph (2) shall be exercisable by statutory instrument.
- (7) For the purposes of section 1 of the Statutory Instruments Act 1946 (definition of "Statutory Instrument"), the power in paragraph (2) is to be taken to be conferred by an Act of Parliament.
- (8) Where an order of the Privy Council under this Order is signified by an instrument purporting to be signed by the Clerk to the Privy Council, that shall be evidence, and in Scotland sufficient evidence, of—
  - (a) the fact that the order was duly made; and
  - (b) the order's terms.

Name Clerk of the Privy Council

Date

## Amendments relating to indemnity arrangements

## PART 1

## Amendments to the Medical Act 1983

1.—(1) For section 44C(a) of the Medical Act 1983(b) (indemnity arrangements) substitute—

## "44C Indemnity arrangements

- (1) A person who holds a licence to practise as a medical practitioner, and practises as such, must have in force in relation to him an indemnity arrangement which provides appropriate cover for practising as such.
  - (2) For the purposes of this section, 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.
- (3) For the purposes of this section, "appropriate cover", in relation to practice as a medical practitioner, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The General Council may make regulations in connection with the information to be provided to the Registrar—
  - (a) by or in respect of a person seeking a licence to practise for the purpose of determining whether, if he is granted such a licence, there will be in force in relation to him by the time he begins to practise an indemnity arrangement which provides appropriate cover; and
  - (b) by or in respect of a registered medical practitioner for the purpose of determining whether there is in force in relation to him an indemnity arrangement which provides appropriate cover.
- (5) Regulations made under subsection (4)(b) may require the information mentioned there to be provided—
  - (a) at the request of the Registrar; or
  - (b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual practitioners or practitioners of a particular description.
- (6) The General Council may also make regulations requiring a registered medical practitioner to inform the Registrar if there ceases to be in force in relation to him an indemnity arrangement which provides appropriate cover.
- (7) The General Council may also make regulations requiring a registered medical practitioner to inform the Registrar if there is in force in relation to him appropriate cover provided under an indemnity arrangement by an employer.
- (8) A licensing authority may refuse to grant a licence to practise to any person who fails to comply, or in respect of whom there is a failure to comply, with regulations made under subsection (4)(a).
- (9) Where a registered medical practitioner is in breach of subsection (1) or there is a failure to comply with regulations made under subsection (4)(b), in relation to him—

<sup>(</sup>a) Section 44C was inserted by 2006/1914.

**<sup>(</sup>b)** 1983 c. 54.

- (a) a licensing authority may withdraw that registered medical practitioner's licence to practise; or
- (b) the breach or failure may be treated as misconduct for the purposes of section 35C(2), and the Registrar may refer the matter to the Investigation Committee for investigation by them under section 35C(4).
- (10) Regulations made under subsections (4), (6) or (7) shall not have effect until approved by the Privy Council.
- (11) This section does not apply to a person who holds a licence to practise as a result of registration under Schedule 2A (visiting medical practitioners from relevant European States).".
- (2) In section  $29F(1A)(\mathbf{a})$  (appeals), in paragraph (a), for "section 44C(7)" substitute "section 44C(8)" and in paragraph (b), for "section 44C(8)(a)" substitute "section 44C(9)(a)".

#### Amendments to the Dentists Act 1984

2. The Dentists Act 1984(b) is amended in accordance with this Part.

## **Amendment of section 18**

3. In subsection (2) of section 18(c) (procedure for registration), after paragraph (b), insert—

"(ba) the documents conferring, or evidencing that there is in force in relation to him, or there will be as necessary for the purpose of complying with section 26A, appropriate cover under an indemnity arrangement.".

## Amendment of section 26A

**4.** For section 26A(**d**)(insurance for dental practitioners), substitute—

### "26A Indemnity arrangements

- (1) A registered dentist who is practising as a dental practitioner must have in force in relation to him an indemnity arrangement which provides appropriate cover for practising as such.
  - (2) For the purposes of this section, an "indemnity arrangement" may comprise—
    - (a) a policy of insurance;
    - (b) an arrangement made for the purposes of indemnifying a person;
    - (c) a combination of the two.
- (3) For the purposes of this section, "appropriate cover", in relation to practice as a dental practitioner, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) Rules may make provision in connection with the information to be provided to the Registrar—
  - (a) by or in respect of a person seeking registration in the register for the purpose of determining whether, if his name is entered in the register, there will be in force in

<sup>(</sup>a) Inserted by S.I. 2006/1914.

**<sup>(</sup>b)** 1984 c. 24.

<sup>(</sup>c) Amended by S.I. 1996/1496; S.I. 2005/2011 and S.I. 2007/3101.

<sup>(</sup>d) Inserted by S.I. 2005/2011.

- relation to him by the time he begins to practise an indemnity arrangement which provides appropriate cover;
- (b) by or in respect of a person seeking restoration of his name in the register for the purpose of determining whether, if his name is restored in the register, there will be in force in relation to him by the time he resumes practice an indemnity arrangement, which provides appropriate cover; and
- (c) by or in respect of a registered dentist seeking retention of his name in the register for the purpose of determining whether, if his name is retained in the register, there will continue to be in force in relation to him an indemnity arrangement which provides appropriate cover.
- (5) Rules may make provision requiring a registered dentist to inform the registrar if there ceases to be in force in relation to that dentist an indemnity arrangement which provides appropriate cover.
- (6) Rules may make provision requiring a dentist to inform the registrar if there is in force in relation to that dentist appropriate cover provided under an indemnity arrangement by an employer.
- (7) Rules made under subsection (4) may require the information mentioned there to be provided—
  - (a) at the request of the registrar; or
  - (b) on such dates or at such intervals as the registrar may determine, either generally or in relation to individual dental practitioners or dental practitioners of a particular description.
- (8) Where a person fails to comply with rules made under subsection (4), or there is a failure to comply with rules made under subsection (4) in relation to him, the registrar may in relation to that person's name—
  - (a) refuse to register it in the register;
  - (b) refuse to restore it to the register; or
  - (c) erase it from the register.
- (9) Where a registered dentist is in breach of subsection (1) or fails to comply with rules made under this section—
  - (a) the registrar may erase that person's name from the register; or
  - (b) the breach or failure may be treated as misconduct for the purposes of section 27, and the registrar may refer the matter to the Investigating Committee for investigation by them under section 27(5)(a).
- (10) Where a person's name has been erased from the register under subsection (8)(c), that name shall be restored to the register on that person's application, if he satisfies the registrar that he meets the requirements of—
  - (a) section 15(3)(a) to (c);
  - (b) this section; and
  - (c) any rules made under section 34B which apply to that person's case.
- (11) This section does not apply to a person who is registered by virtue of section 36 and Schedule 4 (visiting dentists from relevant European States).".

### Amendment of section 36L

**5.** For section 36L(a) (insurance for members of professions complementary to dentistry), substitute—

<sup>(</sup>a) Inserted by S.I. 2005/2011.

#### "36L Indemnity arrangements

- (1) A registered dental care professional who practises as a member of a profession complementary to dentistry must have in force, in relation to each title under which he is registered in the dental care professionals register, an indemnity arrangement which provides appropriate cover for practising as such.
  - (2) For the purposes of this section, an "indemnity arrangement" may comprise—
    - (a) a policy of insurance;
    - (b) an arrangement made for the purposes of indemnifying a person;
    - (c) a combination of the two.
- (3) For the purposes of this section, "appropriate cover", in relation to practice as a member of a profession complementary to dentistry, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) Rules may make provision in connection with the information to be provided to the registrar—
  - (a) by or in respect of a person seeking registration in the dental care professionals register under a particular title (whether or not that person is already registered in that register under any other title or titles) for the purpose of determining whether, if his name is entered in the register under that title, there will be in force in relation to him by the time he begins to practise an indemnity arrangement which provides appropriate cover;
  - (b) by or in respect of a person seeking restoration of his name in the dental care professionals register under a particular title (whether or not that person is already registered in that register under any other title or titles) for the purpose of determining whether, if his name is restored in the register under a particular title, there will be in force in relation to him by the time he resumes practice an indemnity arrangement, which provides appropriate cover; and
  - (c) by or in respect of a registered dental care professional seeking retention of his name in the dental care professionals register under a particular title for the purpose of determining whether, if his name is retained in the register, there will continue to be in force in relation to him an indemnity arrangement which provides appropriate cover.
- (5) Rules may make provision requiring a registered dental care professional to inform the registrar if there ceases to be in force in relation to him an indemnity arrangement which provides appropriate cover.
- (6) Rules may make provision requiring a registered dental care professional to inform the registrar if there is in force in relation to him appropriate cover under an indemnity arrangement provided by an employer.
- (7) Rules made under subsection (4) above may require the information mentioned there to be provided—
  - (a) at the request of the registrar; or
  - (b) on such dates or at such intervals as the registrar may determine, either generally or in relation to individual dental care professionals or dental care professionals of a particular description.
- (8) Where a person fails to comply with rules made under subsection (4), or there is a failure to comply with rules made under subsection (4) in relation to him, in relation to any title in the dental care professionals register, the registrar may with regard to that person's name—
  - (a) refuse to register it in that register under that title;
  - (b) refuse to restore it to that register under that title; or
  - (c) erase it from that register under that title.

- (9) Where a registered dental care professional is in breach of subsection (1) or fails to comply with rules made under this section, the breach or failure may be treated as misconduct for the purposes of section 36N, and the registrar may refer the matter to the Investigating Committee for investigation by them under section 36N(5)(a).
- (10) Where, under subsection (8)(c), a person's name has been erased from the register under a particular title, that name shall be restored to the dental care professionals register under that title on that person's application, if he satisfies the registrar—
  - (a) of Matter D within the meaning of section 36C; and
  - (b) that he meets the requirements of—
    - (i) this section, and
    - (ii) any rules made under section 36Z2 which apply to that person's case.
- (11) This section does not apply to a person who is registered by virtue of section 36Z3 (visiting dental care professionals from relevant European States)".

#### Amendment of Schedule 4A

**6.** In Schedule  $4A(\mathbf{a})$  (registration appeals: dental care professionals register) in paragraph 2(1)(e), for "section 36L(9)(a), (b) or (c)" substitute "section 36L(8)(a)(b) or (c)".

## PART 3

Amendments to the Opticians Act 1989 and related matters

#### Amendment of section 10A

**7.** For section 10A of the Opticians Act 1989(**b**) (insurance for individual registrants and applying for their name to be registered), substitute—

## "10A (Indemnity arrangements for individual registrants and persons applying for their name to be registered)

- (1) A registered optometrist or registered dispensing optician who practises as such (as the case may be) must have in force in relation to him an indemnity arrangement which provides appropriate cover.
  - (2) For the purposes of this section, an "indemnity arrangement" may comprise—
    - (a) a policy of insurance;
    - (b) an arrangement made for the purposes of indemnifying a person;
    - (c) a combination of the two.
- (3) For the purposes of this section, "appropriate cover", in relation to practice as a registered optometrist or registered dispensing optician, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The Council may make rules in connection with the information provided to the Registrar—
  - (a) by or in respect of a person seeking registration in the register of optometrists or dispensing opticians for the purpose of determining whether, if his name is entered in the appropriate register, there will be in force in relation to him by the time he begins to practise an indemnity arrangement which provides appropriate cover;

<sup>(</sup>a) Inserted by S.I. 2005/2011.

**<sup>(</sup>b)** 1989 c. 44.

- (b) by or in respect of a person seeking restoration of his name in the register of optometrists or dispensing opticians for the purpose of determining whether, if his name is restored in the appropriate register, there will be in force in relation to him by the time he resumes practice an indemnity arrangement which provides appropriate cover;
- (c) by or in respect of a registered optometrist or registered dispensing optician seeking retention of his name in the register of optometrists or dispensing opticians for the purpose of determining whether, if his name is retained in the appropriate register, there will continue to be in force in relation to him an indemnity arrangement which provides appropriate cover.
- (5) Rules made under subsection (4)(c) may require the information mentioned there to be provided—
  - (a) at the request of the registrar; or
  - (b) on such dates or at such intervals as the registrar may determine, either generally or in relation to individual registrants or registrants of a particular description.
- (6) The Council may also make rules requiring a registered optometrist or registered dispensing optician to inform the registrar if there ceases to be in force in relation to him an indemnity arrangement which provides appropriate cover.
- (7) The Council may also make rules requiring a registered optometrist or registered dispensing optician to inform the registrar if there is in force in relation to him, appropriate cover provided under an indemnity arrangement provided by an employer.
- (8) Where a person fails to comply with rules made under subsection (4), or there is a failure to comply with rules made under subsection (4) in relation to him, the registrar may with regard to that person's name—
  - (a) refuse to register it in the appropriate register;
  - (b) refuse to restore it to the appropriate register;
  - (c) remove it from the appropriate register.
- (9) Where a registered optometrist or registered dispensing optician is in breach of subsection (1) or fails to comply with rules made under this section—
  - (a) the registrar may remove that person's name from the appropriate register;
  - (b) the breach or failure may be treated as misconduct for the purposes of section 13D(2)(a), and the registrar may refer the matter to the Investigation Committee for investigation by them under section 13D(5).
- (10) Where a person's name has been removed from the appropriate register under subsection (8)(c), that name shall be restored to the appropriate register on that person's application, if the registrar is satisfied that the person meets the requirements of—
  - (a) section 8(1) and (2);
  - (b) this section; and
  - (c) any rules made under section 7,11A or 11B(6) which apply to that person's case.
- (11) This section does not apply to a person who is registered by virtue of section 8B (visiting opticians from relevant European States).".

### Amendment of rule 7

**8.** In the Schedule to the General Optical Council (Registration Rules) Order of Council 2005(a), in rule 7 (additional information required from individual applicants for registration or restoration as an optometrist or a dispensing optician), for paragraphs (e) and (f) substitute—

- "(e) evidence that, if the applicant's name were to be entered in the register, that applicant would have in place appropriate cover under an indemnity arrangement for the purposes of complying with section 10A (indemnity arrangements for individual registrants and persons applying for their name to be registered);
- (f) a copy of that indemnity arrangement or a means of identifying the terms of that indemnity arrangement.".

## Amendments to the Osteopaths Act 1993

#### Amendment of section 37

9. For section 37 of the Osteopaths Act 1993(a) (professional indemnity insurance), substitute—

## "37 Indemnity arrangements

- (1) A registered osteopath (other than a temporarily registered osteopath) who practises as such must have in force in relation to him an indemnity arrangement which provides appropriate cover.
  - (2) For the purposes of this section, an indemnity arrangement may comprise—
    - (a) a policy of insurance;
    - (b) an arrangement made for the purposes of indemnifying a person;
    - (c) a combination of the two.
- (3) For the purposes of this section, "appropriate cover", in relation to practice as a registered osteopath, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The General Council may by rules make provision in connection with the types of indemnity arrangement required and with the provision of information to be provided to the Registrar—
  - (a) by or in respect of any person seeking to be entered in the register as a registered osteopath (including on an application for restoration) for the purposes of determining whether, if that person is so entered, there will be in force in relation to that person by the time that person begins to practise an indemnity arrangement which provides appropriate cover;
  - (b) by or in respect of a registered osteopath for the purposes of determining whether at any time, there is in force an indemnity arrangement which provides appropriate cover in relation to that registered osteopath.
  - (5) Rules under subsection (4)(b) may require information to be provided—
    - (a) at the request of the Registrar; or
    - (b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registered osteopaths or registered osteopaths of a particular description.
- (6) The General Council may also make rules requiring a registered osteopath to inform the Registrar if there ceases to be in force in relation to that registered osteopath an indemnity arrangement which provides appropriate cover.

<sup>(</sup>a) 1993 c. 21.

- (7) The General Council may also make rules requiring a registered osteopath to inform the Registrar if there is in force in relation to that registered osteopath appropriate cover provided under an indemnity arrangement by an employer.
- (8) Where there is a failure to comply with the rules under subsection (4) by or in respect of a person who is entered or is seeking to be entered in the register, the Registrar may refuse to enter the person in, or to restore the person's entry to, the register.
- (9) If a registered osteopath is in breach of subsection (1), or fails to comply with rules under subsection (4)(b), (6) or (7), or there is a failure to comply with rules under subsection (4)(b) in respect of a registered osteopath—
  - (a) the Registrar may remove that person's entry from the register; or
  - (b) the breach or failure may be treated as unacceptable professional conduct and the Registrar may notify the Council .".

## Amendments to the Chiropractors Act 1994

#### Amendment of section 37

**10.** For section 37 of the Chiropractors Act 1994(a) (professional indemnity insurance), substitute—

#### "37 Indemnity arrangements

- (1) A registered chiropractor (other than a temporarily registered chiropractor) who practises as such must have in force in relation to him an indemnity arrangement which provides appropriate cover for practising as such.
  - (2) For the purposes of this section, an indemnity arrangement may comprise—
    - (a) a policy of insurance;
    - (b) an arrangement made for the purposes of indemnifying a person;
    - (c) a combination of the two.
- (3) For the purposes of this section, "appropriate cover", in relation to practice as a registered chiropractor, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and risks of practising as such.
- (4) The General Council may make by rules make provision in connection with the types of indemnity arrangement required and with the provision of information to be provided to the Registrar—
  - (a) by or in respect of any person seeking to be entered in the register as a registered chiropractor (including on an application for restoration) for the purposes of determining whether, if that person is so entered, there will be in force in relation to that person, an indemnity arrangement which provides appropriate cover which commences, at the latest, on the date, when that person starts to practise;
  - (b) by or in respect of a registered chiropractor for the purposes of determining whether at any time, there is in force an indemnity arrangement which provides appropriate cover in relation to that registered chiropractor.
  - (5) Rules under subsection (4)(b) may require information to be provided—
    - (a) at the request of the Registrar; or

10

<sup>(</sup>a) 1994 c. 17.

- (b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registered chiropractors or registered chiropractors of a particular description.
- (6) The General Council may also make rules requiring a registered chiropractor to inform the Registrar if there ceases to be in force in relation to that registered chiropractor an indemnity arrangement which provides appropriate cover.
- (7) The General Council may also make rules requiring a registered chiropractor to inform the Registrar if there is in force in relation to that registered chiropractor appropriate cover under provided under an indemnity arrangement by an employer.
- (8) Where there is a failure to comply with the rules under subsection (4) by or in respect of a person who is entered or is seeking to be entered in the register, the Registrar may refuse to enter the person in, or to restore the person's entry to the register.
- (9) If a registered chiropractor is in breach of subsection (1), or fails to comply with rules under subsection (4)(b), (6) or (7), or there is a failure to comply with rules under (4)(b) in respect of a registered chiropractor—
  - (a) the Registrar may remove that person's entry from the register; or
  - (b) the breach or failure may be treated as unacceptable professional conduct for the purposes of section 20(2) and the Registrar may notify the Council.".

## Amendments to the Health and Social Work Professions Order 2001 and related matters

11. The Health and Social Work Professions Order 2001(a) is amended in accordance with paragraphs 12 to 17.

#### Amendment of article 9

- **12.** In article 9(**b**)(registration)—
  - (a) in paragraph (2), for "Subject to paragraph (3)" substitute "Subject to paragraphs (3) and (3A)";
  - (b) in paragraph (2), after sub-paragraph (b) insert—
    - "(ba) satisfies the Registrar that there is in force in relation to the applicant or there will be as necessary for the purpose of complying with article 11A, appropriate cover under an indemnity arrangement;"; and
  - (c) after paragraph (3) insert—
    - "(3A) Paragraph (2)(ba) does not apply in the case of an applicant seeking admission to that part of the register which relates to the social work profession in England.".

## Amendment of article 10

- **13.** In article 10(c) (renewal of registration and readmission)—
  - (a) in paragraph (2), after sub-paragraph (a) insert—
    - "(aa) satisfies the Registrar that there is in force in relation to the applicant or there will be as necessary for the purpose of complying with article 11A, appropriate cover under an indemnity arrangement;"; and

<sup>(</sup>a) S.I. 2002/254. The title to this statutory instrument was amended by section 213(6) of the Health and Social Care Act 2012

<sup>(</sup>**b**) Amended by S.I. 2007/3101.

<sup>(</sup>c) Amended by S.I. 2007/3101.

- (b) in paragraph (4), after sub-paragraph (a) (but before the following "and"), insert—
  - "(aa) the applicant satisfies the Registrar that there is in force in relation to the applicant or there will be as necessary for the purpose of complying with article 11A, appropriate cover under an indemnity arrangement;"; and
- (c) after paragraph (6) insert—
  - "(7) Paragraphs (2)(aa) and (4)(aa) do not apply to registration as a social worker in England.".

#### Amendment of article 11

- 14. In article 11(lapse of registration), after paragraph (1) insert—
  - "(1A) The rules may—
    - (a) provide for the Registrar to require a registrant to satisfy the Registrar that there is in force in relation to the registrant appropriate cover under an indemnity arrangement;
    - (b) provide for the registrant's name to be removed from the register if the registrant fails to comply with a requirement imposed under sub-paragraph (a).
  - (1B) Rules under paragraph (1A) may require information to be provided—
    - (a) at the request of the Registrar; or
    - (b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registrants or registrants of a particular description.
  - (1C) Paragraph (1A) does not apply to registration as a social worker in England.".

### New article 11A

**15.** After article 11 insert—

#### "Indemnity arrangements

- **11A.**—(1) Each registrant who practises as a member of one of the relevant professions must have in force in relation to that registrant an indemnity arrangement which provides appropriate cover.
- (2) For the purposes of this article and articles 9, 10, 11, 33 and 37, an "indemnity arrangement" may comprise—
  - (a) a policy of insurance;
  - (b) an arrangement made for the purposes of indemnifying a person; or
  - (c) a combination of the two.
- (3) For the purposes of this article and those articles, "appropriate cover", in relation to practice as a member of one of the relevant professions, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The Council may make rules in connection with the information to be provided to the Registrar—
  - (a) by or in respect of a person applying for registration (including readmission) for the purpose of determining whether or not the Registrar is satisfied that if the person is registered, there will be in force in relation to that person, by the time that person begins to practise an indemnity arrangement which provides appropriate cover;
  - (b) by or in respect of a person applying for renewal of their registration for the purpose of determining whether or not the Registrar is satisfied that if the person's registration is renewed, there will be in force in relation to that person, by the time

- that person resumes practice an indemnity arrangement which provides appropriate cover; and
- (c) by or in respect of a registrant in circumstances where, in accordance with rules under article 11(1A), the Registrar requires the registrant to satisfy the Registrar that there is in force in relation to the registrant an indemnity arrangement which provides appropriate cover before the expiry of a specified period.
- (5) The Council may also make rules requiring a registrant to inform the Registrar if there ceases to be in force in relation to the registrant an indemnity arrangement which provides appropriate cover.
- (6) The Council may also make rules requiring a registrant to inform the Registrar if there is in force in relation to the registrant appropriate cover provided under an indemnity arrangement by an employer.
  - (7) If a registrant is in breach of paragraph (1)—
    - (a) the Registrar may remove that person from the register; or
    - (b) the breach may be treated as misconduct for the purposes of article 22(1)(a)(i).
- (8) If an applicant breaches rules under paragraph (4)(a), or there is a breach in respect of the applicant of rules under paragraph (4)(a), the Registrar may refuse the applicant's application for admission (or readmission) to the register.
- (9) If a registrant breaches rules under paragraph (4)(b) or (c), that breach may be treated as misconduct for the purposes of article 22(1)(a)(i).
- (10) For the purposes of this article, relevant profession does not include the social work profession in England.
- (11) This article does not apply to a person who has an entitlement to be registered under article 13A (visiting health professionals from relevant European States).".

## Amendment of article 33

**16.** In article 33 (restoration to the register of persons who have been struck off), after paragraph (2) insert—

"(2A) An application for restoration must be supported by evidence that there is in force in relation to the applicant or will be as necessary for the purpose of complying with article 11A appropriate cover under an indemnity arrangement; but this does not apply to an application for restoration to that part of the register that relates to the social work profession in England.".

### Amendment of article 37

- 17. In article 37(a) (appeals against decisions of the Education and Training Committee)—
  - (a) in paragraph (1), after sub-paragraph (aa) insert—
    - "(ab) removes the name of a registrant from the register on the grounds that the registrant has failed to satisfy the Registrar that there is in force in relation to the registrant appropriate cover under an indemnity arrangement unless that removal is in consequence of a refusal of an application for renewal (including an application for readmission where registration has lapsed);".
  - (b) after paragraph (1), insert—
    - "(1A) Paragraph (1)(ab) does not apply to registration as a social worker in England."; and
  - (c) after paragraph (2), insert—

 $<sup>\</sup>textbf{(a)} \quad \text{Amended by S.I. } 2004/2033, 2007/3101 \text{ and } 2009/1182; \text{and section } 216 \text{ of the Health and Social Care Act } 2012 \text{ (c. 7)}.$ 

- "(2A) No appeal lies to the Council if the complaint of the person aggrieved is, in effect, that a provision of rules under article 7, 9, 10, 11 or 11A is invalid."
- **18.** The Schedule to the Health Professions Council (Registration and Fees) Rules Order of Council 2003(a) is amended in accordance with paragraphs 19 and 20.

#### Amendment of rule 4

- **19.** In rule 4(**b**) (applications for registration), after sub-paragraph (c) (but before the following "and") insert—
  - "(ca) evidence that there is in force in relation to the applicant, or will be as necessary for the purpose of complying with article 11A of the Order, appropriate cover under an indemnity arrangement;".

#### Amendment of Schedule 2

- **20.** In paragraph 1 of Schedule 2 (application for renewal of registration), in paragraph (1), after sub-paragraph (d) insert—
  - "(da) evidence that there is in force in relation to the applicant, or will be as necessary for the purpose of complying with article 11A of the Order, appropriate cover under an indemnity arrangement;".

## PART 7

Amendments to the Nursing and Midwifery Order 2001 and related matters

**21.** The Nursing and Midwifery Order 2001(c) is amended in accordance with paragraphs 22 to 28.

#### Amendment of article 9

- 22. In article 9(d) (registration), in paragraph (2), after sub-paragraph (a) insert—
  - "(aa) satisfies the Registrar that there is in force in relation to the applicant, or there will be as necessary for the purpose of complying with article 12A, appropriate cover under an indemnity arrangement;".

#### Amendment of article 10

- 23. In article 10(e) (renewal of registration and readmission)—
  - (a) in paragraph (2), after sub-paragraph (a) insert—
    - "(aa) satisfies the Registrar that there is in force in relation to the applicant or there will be as necessary for the purpose of complying with article 12A, appropriate cover under an indemnity arrangement;"; and
  - (b) in paragraph (4), after sub-paragraph (a) (but before the following "and") insert—
    - "(aa) the applicant satisfies the Registrar that there is in force in relation to the applicant or there will be as necessary for the purpose of complying with article 12A, appropriate cover under an indemnity arrangement;".

<sup>(</sup>a) S.I. 2003/1572.

<sup>(</sup>b) Amended by S.I. 2004/2524, 2005/1625, 2007/1280 and 2011/210.

<sup>(</sup>c) S.I. 2002/253.

<sup>(</sup>**d**) Amended by S.I. 2007/3101.

<sup>(</sup>e) Amended by S.I. 2007/3101.

#### Amendment of article 12

- 24. In article 12 (lapse of registration), after paragraph (1) insert—
  - "(1A) The rules may—
    - (a) provide for the Registrar to require a registrant to satisfy the Registrar that there is in force in relation to the registrant appropriate cover under an indemnity arrangement;
    - (b) provide for a registrant's name to be removed from the register if the registrant fails to comply with a requirement imposed under sub-paragraph (a).
  - (1B) Rules under paragraph (1A) may require information to be provided—
    - (a) at the request of the Registrar; or
    - (b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registrants or registrants of a particular description.".

#### New article 12A

25. After article 12 insert—

#### "Indemnity arrangements

- **12A.**—(1) Each registrant who practises as a nurse or midwife must have in force in relation to that registrant an indemnity arrangement which provides appropriate cover.
- (2) For the purposes of this article and articles 9, 10, 12, 33 and 37, an "indemnity arrangement" may comprise—
  - (a) a policy of insurance;
  - (b) an arrangement made for the purposes of indemnifying a person; or
  - (c) a combination of the two.
- (3) For the purposes of this article and those articles, "appropriate cover", in relation to practice as a nurse or midwife, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The Council may make such provision in rules in connection with the information to be provided to the Registrar—
  - (a) by or in respect of a person applying for registration (including on application for restoration or readmission) for the purpose of determining whether or not the Registrar is satisfied that if the person is registered, there will be in force in relation to that person, by the time that person begins to practise an indemnity arrangement which provides appropriate cover;
  - (b) by or in respect of a person applying for renewal of their registration for the purpose of determining whether or not the Registrar is satisfied that if the person's registration is renewed, there will be in force in relation to that person, by the time that person resumes practice an indemnity arrangement which provides appropriate cover; and
  - (c) by or in respect of a registrant in circumstances where, in accordance with rules under article 12(1A), the Registrar requires the registrant to satisfy the Registrar that there is in force in relation to the registrant an indemnity arrangement which provides appropriate cover before the expiry of a specified period.
- (5) The Council may also make rules requiring a registrant to inform the Registrar if there ceases to be in force in relation to that registrant appropriate cover under an indemnity arrangement.

- (6) The Council may also make rules requiring a registrant to inform the Registrar if there is in force in relation to that registrant appropriate cover provided under an indemnity arrangement by an employer.
  - (7) If a registrant is in breach of paragraph (1)—
    - (a) the Registrar may remove that person from the register; or
    - (b) the breach may be treated as misconduct for the purposes of article 22(1)(a)(i).
- (8) If an applicant breaches rules under paragraph (4), or there is a breach of rules under that paragraph in respect of the applicant the Registrar may refuse the applicant's application for—
  - (i) admission (or readmission) to the register;
  - (ii) restoration to the register;
  - (iii) renewal.
- (9) If a registrant breaches rules under paragraph (4)(b) or (c), that breach may be treated as misconduct for the purposes of article 22(1)(a)(i).
- (10) This article does not apply to a person who has an entitlement to be registered under article 39 and Schedule 2A (visiting midwives, and certain nurses from relevant European States).".

#### **Amendment of article 33**

- **26.** In article 33 (restoration to the register of persons who have been struck off), after paragraph (2) insert—
  - "(2A) An application for restoration must be supported by evidence that there is in force in relation to the applicant or will be as necessary for the purpose of complying with article 12A appropriate cover under an indemnity arrangement.".

#### Amendment of article 37

- 27. In article 37(a) (appeals against Registrar's decisions)—
  - (a) in paragraph (1), after sub-paragraph (aa) insert—
    - "(ab) removes the name of a registrant from the register on the grounds that the registrant has failed to satisfy the Registrar that there is in force in relation to the registrant appropriate cover under an indemnity arrangement unless that removal is in consequence of a refusal of an application for renewal (including an application for readmission where registration has lapsed);"; and
  - (b) after paragraph (2A), insert—
    - "(2B) No appeal lies to the Council if the complaint of the person aggrieved is, in effect, that a provision of rules under article 7, 9, 10, 12 or 12A is invalid."

#### Amendment of Schedule 2A

- **28.** In Schedule 2A(**b**) (visiting midwives, and certain visiting nurses, from relevant European States), in paragraph 5 (first provision of services: required documents), in sub-paragraph (2), after paragraph (a) insert—
  - "(aa) a written declaration that contains details of the insurance cover, or other means of personal or collective protection, that the practitioner has with regard to professional liability;".

<sup>(</sup>a) Amended by S.I. 2007/3101.

**<sup>(</sup>b)** Inserted by S.I. 2007/3101.

**29.** The Schedule to the Nursing and Midwifery Council (Education, Registration and Registration Appeals) Rules Order of Council 2004(**a**) is amended in accordance with paragraphs 30 to 32.

#### Amendment of rule 5

- **30.** In rule 5(**b**) (application for admission to a part of the register), in paragraph (2), omit the "and" at the end of sub-paragraph (a)(iv) and after paragraph (a) insert—
  - "(aa) evidence that there is in force in relation to the applicant, or will be as necessary for the purpose of complying with article 12A of the Order, appropriate cover under an indemnity arrangement;".

#### Amendment of rule 13

- 31. In rule 13(c) (renewal of registration), in paragraph (1), after sub-paragraph (a) insert—
  - "(aa) evidence that there is in force in relation to the applicant, or there will be as necessary for the purpose of complying with article 12A of the Order, appropriate cover under an indemnity arrangement;".

#### Amendment of rule 15

**32.** In rule 15(**d**) (readmission to the register), in paragraph (2), after "Rules 5(1)" insert ", (2)(aa) and (b)".

## PART 8

Amendments to the Pharmacy Order 2010 and related matters

**33.** The Pharmacy Order 2010(e) is amended in accordance with paragraphs 34 and 35.

## Amendment of article 23

- **34.** In article 23 (form, manner and content of applications for entry or renewal of an entry in the Register: pharmacists and pharmacy technicians), after paragraph (1)(b), insert—
  - "(ba) the document conferring, or the evidence to be provided for the purpose of satisfying the Registrar that there is in force in relation to the applicant or there will be as necessary for the purpose of complying with article 32, appropriate cover under an indemnity arrangement;".

#### Amendment of article 32

**35.** For article 32 (indemnity arrangements), substitute—

## "Indemnity arrangements

- **32.**—(1) A registrant who practises as a pharmacist or pharmacy technician must have in force an indemnity arrangement which provides appropriate cover in relation to that registrant in respect of liabilities which may be incurred in practising as such.
  - (2) For the purposes of this article, an "indemnity arrangement" may comprise—

<sup>(</sup>a) S.I. 2004/1767.

<sup>(</sup>**b**) Amended by S.I. 2007/3101.

<sup>(</sup>c) Amended by S.I. 2005/3354.

<sup>(</sup>d) Amended by S.I. 2007/3101.

<sup>(</sup>e) S.I. 2010/231.

- (a) a policy of insurance;
- (b) an arrangement made for the purposes of indemnifying a person; or
- (c) a combination of the two.
- (3) For the purposes of this article, "appropriate cover", in relation to practice as a pharmacist or pharmacy technician, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.
- (4) The Council may make such provision in rules in connection with the information to be provided to the Registrar—
  - (a) by or in respect of any person seeking to be entered in any part of the Register as a pharmacist or pharmacy technician (including on an application for restoration) for the purposes of determining whether if that person is so entered, there will be in force in relation to that person by the time that person begins to practise an indemnity arrangement which provides appropriate cover;
  - (b) by or in respect of a registrant for the purposes of determining whether, at any time, there is in force an indemnity arrangement which provides appropriate cover in relation to that registrant.
  - (5) Rules under paragraph (4)(b) may require information to be provided—
    - (a) at the request of the Registrar; or
    - (b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registrants or registrants of a particular description.
- (6) The Council may also make rules requiring a registrant to inform the Registrar if there ceases to be in force in relation to that registrant an indemnity arrangement which provides appropriate cover.
- (7) The Council may also make rules requiring a registrant to inform the Registrar if there is in force in relation to that registrant appropriate cover provided under an indemnity arrangement by an employer.
- (8) Where there is a failure to comply with the rules under paragraph (4) by or in respect of a person who is entered, or who is seeking to be entered, in any part of the Register, the Registrar may refuse to enter the person in, or to restore the person's entry to, that part of the Register.
- (9) If a registrant is in breach of paragraph (1), or fails to comply with rules under paragraph (4)(b), (6) or (7), or there is a failure to comply with rules under paragraph (4)(b) in respect of a registrant—
  - (a) the Registrar may remove that person's entry from Part 1, 2, 4 or 5 of the Register (as the case may be); or
  - (b) the breach or failure may be treated as misconduct for the purposes of article 51(1)(a) and the Registrar must consider, in accordance with article 52(1), whether or not to refer the matter to the Investigating Committee or (where rules under article 52(2) so provide) to the Fitness to Practise Committee.
  - (10) Where the Registrar—
    - (a) refuses to enter a person in any part of the Register, or to restore a person's entry to any part of the Register pursuant to paragraph (8); or
    - (b) removes a person's entry from any part of the Register, pursuant to paragraph (9)(a),

the Registrar must send to the person at the person's last known address a statement in writing giving the person notice of the decision and the reasons for it and the right of appeal to the Appeals Committee under article 40.

(11) This article does not apply to a person who is registered by virtue of Schedule 2 (visiting pharmacists from relevant European States). ".

**36.** The Schedule to the General Pharmaceutical Council (Registration Rules) Order of Council 2010(a) is amended in accordance with paragraphs 37 to 39.

#### Amendment of rule 10

- 37. In rule 10 (entry in the register), in paragraph (3), after sub-paragraph (g) insert—
  - "(gg) evidence that there is in force in relation to the applicant, or will be as necessary for the purpose of complying with article 32 of the Order, appropriate cover under an indemnity arrangement;".
- **38.** In rule 11 (renewal of an entry in the Register), after paragraph (4)(a)(ii) insert—
  - "(iia) provide evidence that there is in force in relation to the registrant, or will be as necessary for the purpose of complying with article 32 of the Order, appropriate cover under an indemnity arrangement,".
- **39.** In rule 16 (restoration of an entry in the register), after paragraph (3)(a)(iii) insert—
  - "(iiia) evidence that there is in force in relation to the applicant, or there will be as necessary for the purpose of complying with article 32 of the Order, appropriate cover under an indemnity arrangement,".

## SCHEDULE 2

Article 2(2)

Amendments to and revocations of other subordinate legislation

## Amendment of the National Health Service (General Medical Services Contracts) Regulations 2004

- **1.** In Schedule 6 (other contractual terms) of the National Health Service (General Medical Services Contracts) Regulations 2004(**b**)—
  - (a) in paragraph 122(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 122(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 122(3), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (d) in paragraph 122(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
  - (e) in paragraph 123, for "insurance" substitute "indemnity arrangement".

## Amendment of the National Health Service (Personal Medical Services Agreements) Regulations 2004

- **2.** In Schedule 5 (other contractual terms), for paragraphs 113 and 114 of the National Health Service (Personal Medical Services Agreements) Regulations(c)—
  - (a) in paragraph 113(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";

<sup>(</sup>a) S.I. 2010/1617.

<sup>(</sup>**b**) S.I. 2004/291.

<sup>(</sup>c) S.I. 2004/627.

- (b) in paragraph 113(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
- (c) in paragraph 113(3)(a), for "insurance", substitute "an indemnity arrangement";
- (d) in paragraph 113(3)(a), after paragraph (a) (but before the following "and") insert—
  - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
- (e) in paragraph 113(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
- (f) in paragraphs 114(1) and (2), for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (General Medical Services Contracts)(Scotland) Regulations 2004

- **3.** In Schedule 5 (other contractual terms), for paragraphs 112 and 113 of the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(a)—
  - (a) in paragraph 112(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 112(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 112(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 112(3)(a), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 112(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
  - (f) in paragraph 113, for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (Primary Medical Service Section 17C Agreements)(Scotland) Regulations 2004

- **4.** In Schedule 1 (content of agreements), for paragraphs 76 and 77 of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004(**b**)—
  - (a) in paragraph 76(1), for "hold insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 76(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 76(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 76(3)(a), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the agreement, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 76(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and

<sup>(</sup>a) S.S. I. 2004/115.

**<sup>(</sup>b)** S. S. I. 2004/116.

(f) in paragraph 77, for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

- **5.** In Schedule 6 (other contractual terms), for paragraphs 120 and 121 of the National Health Service (General Medical Contracts) (Wales) Regulations 2004(**a**)—
  - (a) in paragraph 120(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 120(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 120(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 120(3)(a), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 120(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
  - (f) in paragraph 121, for "insurance", substitute "indemnity arrangement".

## Amendment of the Health and Personal Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004

- **6.** In Schedule 5 (other contractual terms) for paragraphs 114 and 115 of the Health and Personal Services, (General Medical Services Contracts) Regulations (Northern Ireland) 2004(**b**)—
  - (a) in paragraph 114(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 114(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 114(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 114(3)(a), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 114(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
  - (f) in paragraph 115, for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (General Dental Services Contracts) Regulations 2005

- 7. In Schedule 3 (other contractual terms) for paragraphs 81 and 82 of the National Health Service (General Dental Services Contracts) 2005(c)—
  - (a) in paragraph 81(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";

<sup>(</sup>a) S.I. 2004/478.

<sup>(</sup>**b**) S.R. 2004 No 140.

<sup>(</sup>c) S.I. 2005/3361.

- (b) in paragraph 81(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
- (c) in paragraph 81(3)(a), for "insurance", substitute "an indemnity arrangement";
- (d) in paragraph 81(3)(a), after paragraph (a) (but before the following "and") insert—
  - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
- (e) in paragraph 81(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
- (f) in paragraphs 82(1) and (2), for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (Personal Dental Services Agreements) Regulations 2005

- **8.** In Schedule 3 (other contractual terms) for paragraphs 79 and 80 of the National Health Service (Personal Dental Services Agreements) Regulations 2005(a)—
  - (a) in paragraph 79(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 79(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 79(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 79(3)(a), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 79(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
  - (f) in paragraphs 80(1) and (2), for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006

- **9.** In Schedule 3 (other contractual terms) for paragraphs 81 and 82 of the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(**b**)—
  - (a) in paragraph 81(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 81(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 81(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 81(3)(a), after paragraph (a) insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 81(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and

<sup>(</sup>a) S.I. 2005/3373.

<sup>(</sup>b) S.I. 2006/490.

(f) in paragraphs 82(1) and (2), for "insurance", substitute "indemnity arrangement".

## Amendment of the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006

- **10.** In Schedule 3 (other contractual terms) for paragraphs 79 and 80 of the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(**a**)—
  - (a) in paragraph 79(1), for "hold adequate insurance", substitute "have in force in relation to it an indemnity arrangement which provides appropriate cover";
  - (b) in paragraph 79(2), for "holds adequate insurance", substitute "has an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 79(3)(a), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 79(3)(a), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the agreement, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;";
  - (e) in paragraph 113(3)(b), for "holding insurance", substitute "having an indemnity arrangement"; and
  - (f) in paragraphs 80(1) and (2), for "insurance", substitute "indemnity arrangement".

## Amendment of the General Ophthalmic Services Contracts Regulations 2008

- 11. In Schedule 1 (other contractual terms) for paragraph 51 of the General Ophthalmic Services Contracts Regulations 2008(b)—
  - (a) in paragraph 51(1) for "hold adequate", substitute "have in force in relation to it";
  - (b) in paragraph 51(1)(a), for "insurance", substitute "an indemnity arrangement which provides appropriate cover";
  - (c) in paragraph 51(1)(b), for "insurance", substitute "an indemnity arrangement";
  - (d) in paragraph 51(2)(a), for "insurance", substitute "an indemnity arrangement";
  - (e) in paragraph 51(2), after paragraph (a) (but before the following "and") insert—
    - "(aa) "appropriate cover" means cover against liabilities that may be incurred by the contractor or subcontractor (as the case may be) in the performance of clinical services under the contract, which is appropriate, having regard to the nature and extent of the risks in the performance of such services;"; and
  - (f) in paragraph 51(2)(b), for "holding insurance", substitute "having an indemnity arrangement".

## SCHEDULE 3

Article 3

## Transitional and saving provisions

## Interpretation

- 1. In this Schedule—
  - (a) "a pre-existing indemnity arrangement" means—

<sup>(</sup>a) S.I. 2006/489.

<sup>(</sup>b) S.I. 2008/1185.

- (i) an adequate and appropriate indemnity arrangement commenced on or before the 24 October 2013; or
- (ii) an adequate and appropriate insurance policy commenced on or before the 24 October 2013:
- (b) a reference to—
  - (i) an old section, an old article or old rule is to that section, article or rule as it had effect immediately before its amendment or substitution by this Order; and
  - (ii) a new section, a new article or new rule is to the section, article or rule as amended or substituted by this Order;
- (c) "the transitional period" means the twelve month period that ends at the end of 24th October 2014.

### Medical Act 1983

- **2.** Subject to paragraph 4, the obligation in the new section 44C(1) (indemnity arrangements) for a person who holds a licence to practise and is carrying out work as a medical practitioner to have an appropriate indemnity arrangement in respect of liabilities which that person may incur in carrying out work as a medical practitioner does not apply during the transitional period where there is a pre-existing indemnity arrangement in respect of that person.
- **3.** Where paragraph 2 applies, the Registrar shall request in writing that a person provides evidence of a pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - **4.** Nothing in paragraph 2 affects the duty of a person who holds a licence to practise—
    - (a) before the end of the transitional period, to comply with the obligation in the new section 44C(1) as it otherwise has effect on or before the expiry date of a pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new section 44C(1) as amended by this Order.

## **Dentists Act 1984**

- **5.** Subject to paragraph 7, the obligation in the new section 26A(1)(indemnity arrangements) for a registered dentist who is carrying out work as a dental practitioner to have an appropriate indemnity arrangement in respect of liabilities which that person may incur in carrying out work as a dental practitioner does not apply during the transitional period where there is a pre-existing indemnity arrangement in respect of that registered dental practitioner.
- **6.** Where paragraph 5 applies, the Registrar shall request in writing that a registered dentist provides evidence of a pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - 7. Nothing in paragraph 5 affects the duty of a registered dentist—
    - (a) before the end of the transitional period, to comply with the obligation in the new section 26A(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new section 26A(1).
- **8.** Subject to paragraph 10, the new obligation in section 36L(1) (indemnity arrangements) for a registered dental care professional who is carrying out work as a member of a profession complementary to dentistry to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a member of a profession complementary to dentistry, does not apply during the transitional period where there is a pre-existing indemnity arrangement in respect of that member of such a complementary profession.

- **9.** Where paragraph 8 applies, the Registrar shall request in writing that the registered dental care professional provides evidence of a pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - 10. Nothing in paragraph 8 affects the duty of a registered dental care professional—
    - (a) before the end of the transitional period, to comply with the obligation in the new section 36L(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new section 36L.

#### **Opticians Act 1989**

- 11. Subject to paragraph 13, the obligation in the new section 10A (indemnity arrangements for individual registrants and persons applying for their name to be registered) for a registered optometrist or registered dispensing optician who are carrying out work as a registered optometrist or registered dispensing optician to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a registered optometrist or registered dispensing optician, does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation that registered optician or registered dispensing optician.
- **12.** Where paragraph 11 applies, the Registrar shall request in writing that the registered optician or registered dispensing optician provides evidence of the pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
- 13. Nothing in paragraph 11 affects the duty of a registered optician or registered dispensing optician—
  - (a) before the end of the transitional period, to comply with the obligation in the new section 10A as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
  - (b) at or after the end of the transitional period, to comply with the new section 10A.
- **14.** Paragraphs (e) and (f) of the old rule 7 of the General Optical Council (Registration Rules) 2005 Rules shall continue to apply for the purpose of paragraph 11.

## Osteopaths Act 1993

- **15.** Subject to paragraph 17, the obligation in the new section 37(1) (indemnity arrangements) for a registered osteopath (but not including a temporarily registered osteopath) who is carrying out work as a registered osteopath to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a registered osteopath, does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation to that registered osteopath.
- **16.** Where paragraph 15 applies, the Registrar shall request in writing that the registered osteopath provides evidence of the pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - 17. Nothing in paragraph 18 affects the duty of a registered osteopath—
    - (a) before the end of the transitional period, to comply with the obligation in the new section 37(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new section 37(1).
- **18.** The old section 37(1) and any rules made under the old section 37(1), shall continue to apply for the purpose of paragraph 15 of this Schedule.

## **Chiropractors Act 1994**

- **19.** Subject to paragraph 21, the obligation in the new section 37(1) (indemnity arrangements) for a registered chiropractor (but not including a temporarily registered chiropractor) who is carrying out work as a registered chiropractor to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a registered chiropractor, does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation to that registered chiropractor.
- **20.** Where paragraph 19 applies, the Registrar shall request in writing that the registered chiropractor provides evidence of the pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - 21. Nothing in paragraph 19 affects the duty of a registered chiropractor—
    - (a) before the end of the transitional period, to comply with the obligation in the new section 37(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new section 37(1).
- **22.** The old section 37(1) and any rules made under the old section 37(1), shall continue to apply for the purpose of paragraph 19 of this Schedule.

#### Health and Social Work Professions Order 2001

- 23. Subject to paragraph 25, the obligation in the new article 11A(1) (indemnity arrangements) for a registrant who is carrying out work as a member of one of the relevant professions to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a member of one of the relevant professions, does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation to that registrant.
- **24.** Where paragraph 23 applies, the Registrar shall request in writing that a registrant provides evidence of the pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - 25. Nothing in paragraph 23 affects the duty of a registrant—
    - (a) before the end of the transitional period, to comply with the obligation in the new article 11A(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new article 11A(1).

## **Nursing and Midwifery Order 2001**

- **26.** Subject to paragraph 28, the obligation in the new article 12A(1) (indemnity arrangements) for a registrant who is carrying out work as a nurse or midwife to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a nurse or midwife, does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation to that registrant.
- **27.** Where paragraph 26 applies, the Registrar shall request in writing that a registrant provides evidence of the pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - 28. Nothing in paragraph 26 affects the duty of a registrant—
    - (a) before the end of the transitional period, to comply with the obligation in the new article 12A(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period, to comply with the new article 12A(1).

### Pharmacy Order 2010

- **29.** Subject to paragraph 31, the obligation in the new article 32(1) (indemnity arrangements) for a registrant who is carrying out work as a pharmacist or pharmacy technician to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a pharmacist or pharmacy technician, does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation to that registrant.
- **30.** Where paragraph 29 applies, the Registrar shall request in writing that a registrant provides evidence of the pre-existing indemnity arrangement to the Council within such period as the Registrar may specify.
  - **31.** Nothing in paragraph 29 affects the duty of a registrant—
    - (a) before the end of the transitional period, to comply with the obligation in the new article 12A(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
    - (b) at or after the end of the transitional period.

#### EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes amendments to the framework legislation for the regulation of doctors, dentists and dental care practitioners, opticians, osteopaths, chiropractors, pharmacists and pharmacy technicians, nurses and midwives, and the professions regulated by the Health and Social Work Professions Council. It makes amendments for doctors, dentists and dental care practitioners, opticians, osteopaths, chiropractors and pharmacists and pharmacy technicians in relation to indemnity arrangements and professional liability insurance and introduces similar arrangements in legislation for nurses and midwives, and professions regulated by the Health and Social Work Council. These changes reflect the requirements under Article 4(2)(d) of directive 2011/24/EC ("the directive") for a Member State of treatment to have in place systems of professional liability cover or similar.

Schedule 1 contains amendments to the legislation regulating health care and associated professions. Part 1 amends the 1983 Act by substituting a new section 44C (indemnity arrangements) which requires medical practitioners to have appropriate cover under an indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a medical practitioner. The amendment also makes it clear that medical practitioner cannot carry out work as medical practitioner unless there is an indemnity arrangement in force in relation to the medical practitioner. The amendments also introduce enabling powers for the Council to make regulations requiring a medical practitioner to inform the Registrar if their cover provided under an indemnity arrangement ceases to be in force, and to inform the Registrar if appropriate cover under an indemnity arrangement is provided by an employer. Failure to comply with the provisions can be dealt with as a ground on which the licence to practise may be withdrawn by the Registrar, or under section 35C(2) and (4) as fitness to practise matter. Consequential amendments are also made to section 29F (appeals).

Part 2 makes similar changes to sections 26A and 36L of the 1984 Act in relation to indemnity arrangements for dentists and dental care practitioners, respectively. In addition, section 18 (registration) is also amended so that it contains a requirement for a dentist to provide documents which satisfy the Registrar that there is, or will be appropriate cover under an indemnity arrangement. Section 28 (restoration of names to the register following erasure under section 27B) and section 36R (restoration of names of the dental care professionals register following erasure under section 36P) also require that the dentist and dental care practitioner, satisfy the Registrar that they meet the requirements under sections 26A and 36L, respectively.

Parts 3 makes similar amendments to section 10A (indemnity arrangements for individual registrants and persons applying for their name to be registered) of the 1989 Act in relation to

indemnity arrangements for optometrists and opticians. It also makes consequential amendments to the 2005 Rules.

Parts 4 and 5 make similar amendments to section 37 in both the 1993 and 1994 Acts in relation to indemnity arrangements for osteopaths and chiropractors, respectively. In particular, it substitutes the requirement to have professional liability insurance, with a requirement to have an indemnity arrangement. There is also a power for the Council to make rules in connection with the types of indemnity arrangement required.

Part 6 amends the 2001(A) Order, so that it contains new requirements in article 11A, for professions regulated by the Health and Social Work Professions Council (other than social workers in England) to have an indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a member of a profession regulated by the Health and Social Work Professions Council. It also makes consequential amendments to the 2003 Rules.

Part 7 amends the 2001(B) Order, so that it contains new requirements in article 12A for nurses and midwives to have an indemnity arrangement in respect of liabilities which may be incurred in carrying out work as a nurse or midwife. It also makes consequential amendments to the 2004 Rules.

Part 8 amends the 2010 Order, so that it contains enabling powers for the Council to make rules requiring a pharmacists and pharmacy technicians to inform the Registrar if their cover provided under an indemnity arrangement ceases to be in force, and to inform the Registrar if appropriate cover under an indemnity arrangement is provided by an employer.

Schedule 2 contains consequential amendments made in respect of other subordinate legislation.

Schedule 3 makes transitional arrangements and savings in relation to the principal measures to allow a pre-existing indemnity arrangement to remain in force during the transitional period provided that the pre-existing indemnity arrangement was commenced on or before the 24 October 2013. Where the pre-existing indemnity arrangement ceases to have effect before the end of the transitional period, then a practitioner must comply with the new provisions on indemnity arrangements.

#### Title: Impact Assessment (IA) Amendment to Healthcare Regulatory Bodies legislation to require registrants to hold professional liability cover as a condition of Date: 01/11/2012 registration Stage: Consultation IA No: 8037 Source of intervention: EU Lead department or agency: Type of measure: Secondary legislation Department of Health Contact for enquiries: Other departments or agencies: Mike Lewis 0113 2546146 Scottish Government, Welsh Government, DHSSPSNI Mike.Lewis@dh.gsi.gov.uk

## **Summary: Intervention and Options**

Cost of Preferred (or more likely) Option							
Total Net Present Value	Business Net Present Value	In scope of One-In, Measure qualifies as One-Out?					
£0m	£m	£1m	No	NA			

**RPC Opinion:** RPC Opinion Status

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

Currently not all statutorily regulated healthcare professionals are required to have in place indemnity arrangements in respect of their practice. Some patients, members of the public and service users might be unable to seek redress in the event of experiencing negligent care from a healthcare professional.

Recent European legislation requires Member States to legislate in relation to indemnity arrangements to be transposed into domestic law by October 2013. Intervention is necessary to implement the legislation as it relates to an individual registered healthcare professional. Failure to transpose could lead to heavy fines for the UK Government. As this is driven by EU legislation, it is out of scope of One-In, One-Out.

## What are the policy objectives and the intended effects?

The policy objective is to put in place a system that complies with Directive 2011/24/EU and in doing so, to ensure that, when harm has been caused through negligence on the part of a healthcare professional, patients, the public or service users should have means of redress. The intended effect is to require all healthcare professionals to have an indemnity arrangement in place (either arranged personally or in place as a result of their employment status). Unless healthcare professionals can demonstrate that such arrangements are in place they will be unable to register as a healthcare professional and so be unable to practise.

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

Option 1: Introduce new, consistent, legislative requirements across the regulators requiring registrants to have an indemnity arrangement in place as a condition of registration.

Three further options were considered: 'Do nothing', rely on regulators' guidance to registrants to have indemnity arrangements, and repealing existing legislation; or rely on existing legislation and introducing new legislation for Regulators who do not currently have it.

Only the option above delivers the policy objectives of meeting the obligations placed on Member States under Article 4 (2)(d) of the EU Directive on Patients Rights in Cross Border Healthcare in respect of individual healthcare professionals, as well as implementing the recommendations of the Independent Review Group (IRG)

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 10/2018							
Does implementation go beyond minimum EU requirements?							
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.  Micro < 20 No No				<b>Medium</b> Large No No			
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b> NA	Non-traded: NA		raded:	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY:	Date:	
· · · · · · · · · · · · · · · · · · ·		

## **Summary: Analysis & Evidence**

**Description:** 

#### **FULL ECONOMIC ASSESSMENT**

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)				
<b>Year</b> 2012	<b>Year</b> 2012	Years 10	Low: Optional	High: Optional	Best Estimate: 0		

COSTS (£m)	<b>Total Tra</b> (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	<b>Total Cost</b> (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	0		1.0	8.6

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

The chief costs are to individual practitioners who do not already have indemnity cover in obtaining cover...

An estimated 4195 practitioners will be impacted, each incurring an estimated average cost of £240 per year, a total cost of £1m per year. Given that costs will be incurred by self-employed individuals, it is possible that these additional costs will be passed on to patients.

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

Small impact to employers due to administrative costs of providing evidence of cover to regulatory bodies. Regulators will incur compliance, compliance testing and enforcement costs. Consultation seeks data to quantify these costs.

Transaction costs of insurance/indemnity provision (chiefly administrative) will be incured by registrants and providers of cover

BENEFITS (£m)	Total Tra (Constant Price)	ansition Years	Average Annual (excl. Transition) (Constant Price)	<b>Total Benefit</b> (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate			1.0	8.6

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

Additionally, on the assumption of an actuarially fair market, the costs to individuals of obtaining cover will be offset by the benefit received by patients in claims, together with the benefit to the providers of insurance and indemnity in terms of the increased income from premiums, with the profit that ensues. thus resulting in an overall cost neutral transaction. The consultation invites respondents to provide data to test and validate these assumptions.

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

Patients will benefit from recourse to redress in the event of experiencing negligent care and from the general assurance that will result from the knowledge that all practitioners have appropriate cover in place.

Professionals will experience the benefits that result from insurance cover.

Tax payers will benefit through not having to meet costs incurred due to negligent care provided by professionals operating without cover.

#### Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Assumptions made for estimation of impact will be tested and validated by consultation.

All employed individuals covered by employers arrangments, including CNST and equivalent schemes. Self employed individuals without cover estimated to be 4195, with proxy cost of cover estimated at £240 - the average costs of obstaining cover via professional body membership.

Costs balanced by benefits resulting in a net present value of zero.

## **BUSINESS ASSESSMENT (Option 1)**

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 1	Benefits: 1	<b>Net:</b> 0	No	NA

## References

- (1) <u>Directive 2011/24/EU Of The European Parliament And Of The Council Of 9 March 2011 On The Application Of Patients' Rights In Cross-Border Healthcare</u>
- (2) Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional Government response: DH, July 2010 <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_117454">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_117454</a>
- (3) Response to the Independent Review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional; DH, December 2010 <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH">http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH</a> 122 611

## **Notes**

## **RPC Opinion Status**

A Regulatory Triage Assessment (RTA) was submitted to the Regulatory Policy Committee to seek fast track clearance as "deregulatory" representing an overall simplification of legislation being across the healthcare professional regulatory bodies.

The Regulatory Policy Committee commented that the

'RTA does not appear to provide sufficient evidence that the proposal is deregulatory. There is evidence to suggest that this proposal instead represents an increase in regulatory requirements with direct costs to business of over £1m and therefore appears to require a full IA to be submitted instead of a RTA.'

In light of these comments, the enclosed consultation paper has been amended and this supporting consultative Impact Assessment has been prepared, which acknowledges that there is a shortage of reliable data with regard to the extent of indemnity cover and cost in the private sector. Accordingly a series of assumptions have been made to estimate the impact of the proposals. Respondents to the consultation are invited to provide data to test and validate the assumptions in order to complete a full Impact Assessment. Following consultation this will be submitted for clearance before publication.

## Organisations in Scope

It should be noted that, as the legislation relates to requirements for individual healthcare professionals to hold an indemnity arrangement, organisations are not considered to be in scope of the legislation.

Whilst there may be a direct impact on the affected healthcare professional regulatory bodies, the consultation seeks additional information to quantify this and to test and validate the assumptions relating to the costs and benefits to business.

## **Evidence Base**

## PROBLEM UNDER CONSIDERATION

- 1. The four UK Health Departments are aware of concerns that have arisen about the fact that some healthcare professionals currently practice without indemnity or insurance cover, or with insufficient cover, and that in such circumstances those whom they treat may be left without means to seek redress in the event of a negative incident negligently caused by the activities of a healthcare professional(s). Individual tragedies caused by negligence should not be compounded by this.
- 2. Recent European legislation requires Member States to have in place requirements in relation to indemnity arrangements in the health sphere. Member States are required to transpose this legislation into domestic law by October 2013. Meeting this requirement subsumes the existing policy objective set out above.
- 3. Therefore, the problem under consideration is how to put in a place a system to ensure that those harmed by the negligent activities of healthcare professionals have a means to redress, that meets the requirements of European Law.

## **BACKGROUND**

## EU DIRECTIVE 2011/24/EU ON PATIENTS RIGHTS IN CROSS BORDER HEALTHCARE

- 4. Following negotiation 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 now have until October 2013 to transpose the Directive's requirements into their national laws. Negotiation around the content of the Directive was taking place whilst an Independent Review Group was reviewing the domestic policy, although the Directive was not formally approved until after it reported.
- 5. The Directive sets out at Article 4(2)(d) that Member States shall ensure:'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'
- 6. In its definitions, the Directive sets out that:

Article 3(a) 'healthcare' 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 healthcare 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.

## DOMESTIC CONCERNS ON LACK OF INDEMNITY COVER FOR HEALTHCARE PROFESSIONALS

- 7. Domestic concerns about professional indemnity predate the introduction of European requirements in this area. 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.
- 8. In March 2004, the then Minister of State for Health decided to proceed with compulsory indemnity on the basis that it was unreasonable for individual tragedies to be compounded by the injustice of being unable to secure compensation. Accordingly legislation began to be introduced on a regulator by regulator basis.
- 9. In another case, in 2005, harm was caused to a mother and baby by an independent midwife, resulting in permanent disability for the child and reconstructive surgery for the mother. In seeking redress subsequently, it became apparent that the midwife had failed to inform her clients that she had no cover. As she had no assets, any attempt to seek redress in court would not have resulted in compensation to the patients.
- 10. There are 32 groups of healthcare professionals (the Healthcare Professionals) who must be registered by one of nine statutory healthcare professional regulatory bodies in order to practise their profession.<sup>1</sup>
- 11. There is currently no consistency across the healthcare professional regulatory bodies with regard to legislation or guidance on the need for individual regulated healthcare professionals to hold insurance or indemnity cover (an indemnity arrangement).
- 12. Therefore, in terms of the current position on insurance and indemnity, the healthcare professional regulatory bodies fall into three groups:
  - A. Those whose guidance insists on insurance or indemnity (when in active practice in the case of the General Chiropractic Council) 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.
- 13. 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 this Order.
- 14. The four UK Health Departments believe that it is unacceptable for individuals not to have access to recourse to compensation where they suffer harm through negligence on the part of a healthcare professional.<sup>2</sup>

5

<sup>&</sup>lt;sup>1</sup> Annex A of this consultation paper details the Regulators and which groups of healthcare professionals they regulate, together with number of registrants and indemnity provision.

- 15. In 2009, the previous administration sought to introduce requirements to have an indemnity arrangement in place to nurses and midwives, but concerns were raised about the proposed model of implementing such a requirement.
- 16. In response, an Independent Review Group (made up of representatives from healthcare professional regulatory bodies, professional bodies, patient/public representatives and other interested parties) was established by the then Secretary of State for Health in England, with the support of Ministers in Northern Ireland, Scotland and Wales to take forward work arising from the Review. The Independent Review Group was led by Finlay Scott, the former Chief Executive of the GMC.
- 17. The specific purpose of the Independent Review Group's work was to make recommendations to Government as to whether requiring healthcare 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.
- 18. In order to asses 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 healthcare professionals.
  - identify the practicalities of minimising associated costs to ensure that the impact is as proportionate as possible.
- 19. However, as set out in the Independent Review Group Report, 'it proved impossible to formulate conventional cost benefit analysis..... There was an almost complete absence of reliable data on the incidence and scale of failures to secure compensation because adequate assets were not available.'3
- 20. Pricewaterhouse Coopers also found that details of insurance and indemnity cover premiums are not widely available, due to its "commercial in confidence" nature.
- 21. In light of this the Independent Review Group considered an alternative cost basis of:
  - a. Compliance the costs incurred by registrants in satisfying the requirement to have insurance or indemnity.
  - b. Compliance testing the costs incurred by regulators in determining whether registrants satisfy the requirement to have insurance or indemnity.
  - c. Enforcement the costs incurred by regulators when the requirement to have insurance or indemnity is not satisfied.<sup>4</sup>
- 22. After consideration of the issues the Independent Review Group concluded that:

<sup>&</sup>lt;sup>2</sup> The NHS Constitution in England reinforces this by including the "right to compensation where you have been harmed by negligent treatment".

<sup>&</sup>lt;sup>3</sup> Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page 13

<sup>&</sup>lt;sup>4</sup> Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010 page14

'making insurance or indemnity a statutory condition of registration is the most cost effective and proportionate means of achieving the *policy* objective' <sup>5</sup>

- 23. The Independent Review Group also concluded that such a requirement would best work as follows:
  - a. A statutory condition of registration would apply equally and unequivocally to all registered healthcare 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 healthcare 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."<sup>6</sup>
- 24. The Independent Review Group reported shortly after the General Election in May 2010. The incoming Government and the Devolved Administrations welcomed the findings of the Independent Review Group and accepted its conclusions and recommendations.
- 25. Subsequently the Government stated in its Command Paper Enabling Excellence (published in February 2011)<sup>7</sup> that:-

'The Coalition Government and the Devolved Administrations believe that the requirement that healthcare professionals should hold insurance or indemnity cover should be consistent across health regulation, and that introduction of any requirements should not be framed so as to require individual employees to obtain personal cover themselves when they are already covered by corporate or employer cover.'

- 26. The Independent Review Group recommendations provide a framework within which the provisions of Article 4(2)(d) of Directive 2011/24/EU can be implemented, without going beyond the requirements of the Directive.
- 27. The consultation which this impact assessment supports does not, therefore, consider the appropriateness of a requirement for healthcare professionals to have in place an indemnity arrangement as a condition of registration. The reason for this is that the four UK Health Departments, cognisant of the need to implement the Directive and after consideration of the work of the Independent Review Group, believe that it is right and proper to introduce such a requirement to provide better and more consistent protection to patients and the public. Instead, this consultation focuses on assessing the implementation and impact of the policy.

<sup>&</sup>lt;sup>5</sup> 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

<sup>&</sup>lt;sup>6</sup> 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

<sup>&</sup>lt;sup>7</sup> Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff DH 2011, p20

- 28. The Impact Assessment has been drawn up using the best available data to make a series of assumptions. However, it should be emphasised that, in the absence of reliable data as indicated above, there is a need to source further information, if available, and refine the data in order to test and validate the assumptions. Accordingly, the consultation asks a series of questions inviting respondents to provide information to assist in the development of a full Impact Assessment.
- 29. As the scope of the Order is limited to individual regulated healthcare professionals, it does not address the question of indemnity cover for corporate health providers. Issues around corporate health providers will be addressed as part of the transposition of the other elements of the Directive, which will be consulted on separately.
- 30. The Scottish Government has recently completed a public consultation on the recommendations of the No-fault Compensation Review Group which was established in 2009. The 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 the scheme. The Review Group also recommended that the scheme should extend to all registered healthcare professionals in Scotland, not simply to those employed by NHS Scotland. The responses to the consultation are currently being considered.

#### **RATIONALE FOR CHANGE**

31. Because of the multiple ways in which healthcare is delivered in the UK, there is a mixed economy in terms of ways in which redress might be sought in the event of negligent harm. As research commissioned by the Independent Review Group stated:

'For Healthcare Professionals who are employed or engaged directly by a NHS hospital/acute trust, there is provision of [an indemnity arrangement] through the National Health Service Litigation Authority (NHSLA) schemes, and similar schemes in Scotland, Wales and Northern Ireland.

However, where Healthcare Professionals are employed by another organisation, or are conducting work on a self-employed basis, either independently or for the NHS (including independent contractors in primary care (e.g. GPs) or through sub contracts), cover is varied...

- ...Some professional or regulatory bodies require members to have [an indemnity arrangement] as part of their registration, but the level of implementation varies.<sup>8</sup>
- 32. Tying registration as a healthcare professional to possession of an indemnity arrangement is a proportionate way in which to achieve the policy objectives.

#### **ASSUMPTIONS, RISKS, AND ISSUES**

#### Who will be impacted?

33. The following categories of groups will potentially be impacted by these proposals:-

 Healthcare 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;

<sup>&</sup>lt;sup>8</sup> Source: <u>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 13</u>

- Employers of Healthcare Professionals: A limited impact is assumed, due to the administrative costs of providing evidence of cover to the regulatory bodies;
- Patients and Service Users: This group would benefit by assurance that, should a negligent action by a healthcare 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 healthcare professionals were already required to hold an indemnity arrangement;
- The Public and Taxpayers: In addition to the benefits for patients and service
  users, this group would benefit by reduced costs to the public purse of meeting
  certain care and support services that are provided on a means tested basis for
  patients following adverse incidents due to the negligent actions of healthcare
  professionals who do not have an indemnity arrangement in place; and
- The Healthcare Professional Regulatory Bodies: As the Independent Review Group envisaged, there might be compliance testing and enforcement costs resulting from these policy proposals. With regard to compliance testing, these have not as yet been quantified. The report however indicated that the impact associated with enforcement would be minimal or reduced as action could be taken via low cost administrative measures as opposed to high cost fitness to practise procedures.
- Providers of Indemnity cover: These would benefit from the increased business received due to the policies that individual healthcare professionals would be required to obtain.

#### **Proportionality**

34. When considered in isolation, the introduction of a requirement for all 1.4 million healthcare professionals to have an indemnity arrangement in place as a condition of their registration might raise significant concerns as to cost implications. However, it is vital to stress that there is no intention to introduce duplication through these proposals. That is, for instance, if a healthcare professional benefits from an indemnity arrangement as provided through their employer this would be sufficient to meet the requirement for registration as a healthcare 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.'

- 35. 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 healthcare professional.
- 36. Therefore, for avoidance of doubt, the draft legislation to which this impact assessment refers does not intend, or require, individuals to take out additional or duplicate cover when a sufficient indemnity arrangement is already in place. Clearly, this would be disproportionate.

<sup>&</sup>lt;sup>9</sup> 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

#### Alternatives to Regulation

- 37. 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 ends as is intended. Principally, we have explored whether or not the healthcare 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 healthcare professional regulatory body would respond accordingly.
- 38. This proposal was regarded 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.

#### **OPTIONS APPRAISAL**

- 39. Consideration was also given at the options analysis phase to both a 'do nothing option' and the use of existing legislation with the introduction of new legislation for the HCPC and NMC.
- 40. The 'do nothing' option is not feasible as it would not meet the requirements of the Directive. There would be no means of the member state ensuring that a system of professional indemnity cover was in place for all healthcare professionals and the UK Government would be at risk of infraction by the European Court of Justice. Therefore, in line with guidance from the Department of Business, Innovation and Skills, the 'do nothing' option has not been included in this consultative Impact Assessment.
- 41. The use of existing legislation would have perpetuated a piecemeal approach to the issue and would lack consistency across the healthcare 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.
- 42. As a result only one option remains feasible and has been appraised.

# Option 1: Introduce new, consistent, legislative requirements across all the healthcare professional regulatory bodies to require Healthcare Professionals to have an indemnity arrangement in place as a condition of registration.

- 43. This Option implements the key recommendations of the Independent Review Group through new legislation, consistent across all the healthcare professional regulatory bodies, which:-
  - Introduces a requirement for healthcare professionals to have an indemnity arrangement in place (as required by Article 4(2)(d) of the Directive);
  - Provides healthcare professional regulatory bodies with a power to make rules on:-
    - What information needs to be provided by healthcare professionals, and when, to demonstrate that they have an indemnity arrangement in place in order to practise;
    - Requirements for healthcare professionals to inform their healthcare professional regulatory body should cover under an indemnity arrangement cease; and,
    - Requirements for healthcare professionals to inform their healthcare professional regulatory body if the source of their indemnity arrangement is one provided by an employer;
  - Gives healthcare professional regulatory bodies the ability to refuse to allow a healthcare professional to join, remain on, or return to, their register; and,
  - Permits healthcare professional regulatory bodies to either administratively remove a healthcare professional from their register, or take fitness to practise action against them, in the event of there not being an indemnity arrangement in place.

#### Estimating the number of healthcare professionals impacted by the policy

- 44. It is difficult to estimate the number of healthcare 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). As has been set out above, there is an absence of reliable data. For the purposes of this consultative Impact Assessment, a series of assumptions have been made using the best available data from a range of sources. The consultation document specifically invites respondents to submit further information to test and validate these assumptions.
- 45. In order to estimate the number of practitioners potentially impacted by the policy change, the following methodology has been used:
  - i. Identify those professional groups which are most likely to be impacted by the policy change.
  - ii. Identify the number in each professional group working in the private sector, based on data from the Office of National Statistics, supported by registration data from healthcare professional regulatory bodies.
  - iii. Separately identify employees / employed staff, based on data from the Office of National Statistics and registration data from healthcare professional regulatory bodies.
  - iv. For each group, estimate the proportion of staff who are members of a professional body which provides indemnity cover, based on membership data of professional bodies as a proportion of total registrants.
  - v. Identify the groups of staff where coverage at step (iv) is not 100%
  - vi. Estimate the number of individuals impacted, i.e. self-employed and not otherwise holding an indemnity arrangement, using proportions calculated at step (iv).

#### Step (i) Professional Groups

46. 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 the Table 1 are those which might be most likely to need an indemnity arrangement.

Table 1
Relative risk indication

Category of Healthcare professional	Number of registrants	Estimated proportion who work outside the NHS**		
Registered with GMC	231,291			
Registered with GDC	92,976			
Registered with NMC	665,704			
Registered with GOC	23,319	•		
Registered with GOsC	4,187	•		
Registered with GCC	2,489	•		
(Previously) Registered with RPSGB	58,220			
Registered with PSNI	2,200			
Arts therapist	2,768	•		
Biomedical scientists	21,786			
Chiropodist/podiatrist	12,876			
Clinical scientist	4,394			
Dietician	7,137			
Occupational Therapist	30,127			
Operating Department Practitioner	10,048			
Orthoptists	1,263			
Paramedic	15,589		Table k	rev
Physiotherapist	44,734		Table	Proportion working
Practitioner psychologists	15,244		Rating	outside of NHS
Prosthetist / orthotist	865			0 – 10%
Radiographer	26,319			10 – 75%
Speech and language therapists	12,298	•		75 – 100%

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

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 32

- 47. Of the professions identified as red or amber, only the following are regulated by bodies whose guidance does not already insist on insurance or indemnity, and nor is it a mandatory requirement (as noted in paragraph 12). These categories are in scope for the impact analysis as at step (i):
  - Psychologists
  - Nurses
  - Midwives
  - Paramedics
  - Medical Radiographers
  - Chiropodists

- Physiotherapists
- Occupational Therapists
- Speech And Language Therapists
- Therapists not elsewhere classified (excluding Chiropractors or Osteopaths).
- 48. In general, healthcare professionals who are employed or engaged by the public sector would have an indemnity arrangement in place through their public sector employer. Therefore, means for redress would naturally exist, so such individuals are considered to be out of scope for the impact analysis.

#### Step (ii) Individuals working in the private sector Step (iii) Self employed private sector healthcare professionals

49. Step (ii) was to identify how many individuals work in each of the professional groups within scope in the private sector, with step (iii) refining the data to identify those working in a self-employed capacity. Those who are employed are assumed to have an indemnity arrangement in place through their employer. Data from the Office of National Statistics (ONS) as set out in Table 2 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 2 Public and Private Employment Figures

	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				
DPHTHALMIC 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										
IURSES	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 <sup>1</sup>	48	8	39		21	21				
. PERSONAL SERVICE OCCUPATIONS										
11. 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	711	2-12	25		37 -	014				

Footnotes

Source: Labour Market Survey

<sup>-</sup> Estimates have been suppressed due to sample size. Small values are replaced by "\*", zero estimates are shown with "-".

<sup>-</sup> Highlighted cells show groups not currently required to hold indemnity arrangements.

<sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> Estimate of the total number of professionals not required by statute or code of conduct to hold insurance or indemnity

- 50. 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.
- 51. Accordingly, a table for those professional groups in scope has been produced (Table 3). This includes a line for "Therapists not elsewhere classified based on regulator data". This is based solely on data for regulated healthcare professional therapists who are not currently required to hold an indemnity arrangement. This comprises data for Arts Therapists, Biomedical and Clinical Scientists, Dietitians, Orthoptists and Prosthetists and Orthotists, using registrant data from the HCPC, the healthcare professional regulatory body responsible for these therapists, and identifies 12 thousand self-employed individuals.

**Table 3** Public and Private Employment Figures for self-employed Healthcare Professionals not currently required to hold an indemnity arrangement

		UK						
		Private			Public			
PROFESSIONAL GROUP	ALL	Employee	Self Employed		ALL	Employee	Self Employed	
PSYCHOLOGISTS	6	1	5		24	24		
NURSES	83	80	3		426	426		
CHIROPODISTS	6	-	6		34	34		
PHYSIOTHERAPISTS	14	5	9		21	21		
OCCUPATIONAL THERAPISTS	3	2	1		20	20		
SPEECH AND LANGUAGE THERAPISTS	2	1	1		5	5		
THERAPISTS NEC BASED ON REGULATOR DATA 1	15	2	12		38	38		
	129	91	37		530	530		
TOTAL SELF EMPLOYED NOT REQUIRED TO HOLD INSURANCE/INDEMNITY 2	-	-	37					

Source: Labour Market Survey and Regulatory Body data

52. This assessment of self-employed regulated healthcare professionals in scope of the consultative Impact Assessment at step (iii) provides a total of 37,000.

#### **Independent Midwives**

- 53. The number of self-employed midwives is suppressed in ONS data due to the small number involved. For 2011-12, 170 individuals have declared their intention to practice to the NMC<sup>10</sup>. Whilst these individuals are currently unable to obtain individual indemnity or insurance cover, independent research commissioned by the Nursing and Midwifery Council and Royal College of Midwives<sup>11</sup> has suggested that independent midwives would be able to obtain insurance as employees within a corporate structure. We know this model of maternity care delivery is viable because midwives operating such models have been able to purchase insurance for the whole of the midwifery care pathway and are delivering maternity services, both inside and outside the National Health Service.
- 54. It is understood that this model is being explored with a view to encompassing the majority of independent midwives.

<sup>1</sup> Therapists not elsewhere classified includes the following professional groups: Arts Therapists, Biomedical Scientists, Clinical Scientists, Dieticians, Operating Department Practitioners, Orthoptists and Prosthetists/Orthotists. Split based on ONS ratios

<sup>&</sup>lt;sup>2</sup> Estimate of the total number of professionals not required by statute or code of conduct to hold insurance or indemnity.

Local Supervisory Authority data, NMC 2012

Local Supervisory Nationly data, 14110 2012

<sup>&</sup>lt;sup>11</sup> Flaxman Partners: <u>The Feasibility and Insurability of Independent Midwifery in England</u> 2011

- 55. Furthermore, the Department of Health in England is currently reviewing NHS indemnity arrangements with regards to opening up the Clinical Negligence Scheme for Trusts (CNST) to non-NHS bodies delivering NHS care.
- 56. Accordingly, given the small scale of the professional group, the assumption made for the purposes of the Impact Assessment is that the majority of independent midwives will be able to obtain cover via one of the routes set out above, although it may require midwives to change the governance framework for their care and their delivery practices to comply with an indemnity policy.
- 57. We will be seeking further information on the validity of this assumption as part of the consultation exercise and are asking a specific question for this purpose. This and other specific questions are set out at Annex B.

#### Step (iv) Professional body arrangements for cover

58. All the groups in scope have associated professional bodies, many of which provide an indemnity arrangement as a benefit. Analysis in Table 4 of the data at step (iv) shows that all psychologists, chiropodists, physiotherapists and speech and language therapists may be considered to be members of professional bodies that include indemnity cover as a benefit of membership.

59.

Table 4 Professional Body Indemnity coverage

Profession	Number of Registrants <sup>1</sup>	Number registered with professional body offering Indemnity Arrangements (excluding professional bodies where membership is currently unknown) <sup>2</sup>	% of practitioners covered via professional body membership (assumed 100% where no. of members exceeds no. of registrants)
Psychologists <sup>3</sup>	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 classified elsewhere (exc. chiropractors and osteopaths)	52,314	39,150	75%

#### Notes:

- 1 Source HCPC website September 2012
- 2. Source Relevant professional body websites Summer 2012 Details in accompanying spreadsheet.
- 3. Psychologists registered with professional body include a range of disciplines including educational and sports psychiatrists
- 60. In a number of cases, the number of persons holding indemnity cover with professional bodies exceed the number of registrants in size. This is due to a range of factors, chiefly where non-practising professionals remain part of the professional body or where there are more than one professional association and registrants can be a member of more than one. With regard to Psychologists, there are certain groups who are not subject to

statutory professional regulation, such as educational or sports psychologists, but who may be members of professional bodies.

#### Step (v) Groups without full cover from professional bodies

61. Accordingly, at step (v) it is assumed that the groups still within scope comprise nurses, occupational therapists and therapists not elsewhere classified.

## Step (vi) Estimated number of self-employed healthcare professionals without benefit of indemnity arrangement through membership of a professional body

62. By examining the data from step (iii) in relation to the remaining groups where numbers holding cover from professional bodies was lower than numbers registered with a professional regulator, an estimated total of 16,173 individual self-employed healthcare professionals who currently do not hold any form of indemnity and who will be required to take out insurance or indemnity as a result of the proposed new legislation is reached. This figure is then reduced in line with the estimated proportion of practitioners covered by regulatory body membership (derived from step (iv)) for each professional group, as set out at Table 5.

**Table 5** Estimated number of self employed healthcare professionals without an indemnity arrangement.

Profession	Number of self- employed, private sector practitioners, with therapists based on professional body/regulator data, mid point calculation	Estimated % of self- employed practitioners covered via 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	65%	1,040	
Occupational Therapists	1,000	91%	92	
Therapists not classified elsewhere remaining in scope	12,173	75%	3,063	
TOTAL	16,173		4,195	

Source: DH calculations

63. We therefore estimate the policy will have an impact on up to 4,195 self-employed individuals, who will be required in future to hold an indemnity arrangement who do not currently do so. We will review the assumptions underpinning our analysis following the consultation. It may be for example that, as part of competent business practice, self-

- employed individuals-are more likely to have some form of public liability insurance or professional indemnity insurance in place.
- 64. As part of the consultation exercise, respondents are invited to submit further data to test and validate these assumptions, with specific questions as set out in Annex B:

#### **Estimating costs**

#### To Healthcare professionals

65. As has been set out above, data on the cost of insurance and indemnity is not readily available, owing to the "commercial in confidence" nature. Accordingly, for the purposes of estimating costs in this consultative Impact Assessment, a proxy cost has been used, based on the cost of professional association membership with indemnity cover as a benefit. Using this proxy, should cover not be in place for any of the individuals identified above, we estimate annual costs would be as follows.

**Table 6** Estimated cost of obtaining indemnity cover

Profession	Estimated number of self- employed, private sector practitioners without cover <sup>1</sup>	Individual cost of professional body membership	Total estimated cost impact of professional body membership for professionals affected by the proposed new requirement
Nurses	1,040	£195²	£203,000
Occupational Therapists	92	£256³	£23,000
Therapists not classified elsewhere			
remaining in scope	3,063	£255 <sup>4</sup>	£780,000
TOTAL	4,195	£240 <sup>5</sup>	£1,006,000

Notes 1: Source: DH estimates on numbers as calculated above at step (vi)

- 66. The cost of £1,006,000 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.
- 67. As part of the consultation exercise, respondents are invited to submit further data to test and validate these assumptions as indicated in the questions set out in Annex B.

#### To Healthcare Professional Regulatory Bodies

68. For the healthcare professional regulatory bodies, estimating the expected cost is complicated given that the draft legislation under consideration provides the healthcare

<sup>2.</sup> Source. Royal College of Nursing website

<sup>3.</sup> Source: British Association of Occupational Therapists website

<sup>4,</sup> Source DH calculation of average cost for Therapists in scope.

<sup>5</sup> Mean cost

professional regulatory bodies with enabling powers to make further legislation on how registration as a healthcare professional should be tied to possession of an indemnity arrangement for their particular body. Therefore, as implementation is a matter for each health care professional regulatory body as an independent statutory body, and because they will need to refine their own proposals, consult on them, and assess impact separately, the Impact Assessment cannot be definitive on implementation costs at this stage. The following cost calculations are therefore provided on an indicative basis only.

69. The variety of potential approaches by the healthcare professional regulatory bodies to implementing these proposals is supported by the Research Report of the Independent Review Group. The estimated costs of implementation for the individual healthcare professional regulatory bodies at that time were as follows:

**Table 7** Healthcare Professional Regulatory Body –Estimated Cost of implementation of compliance monitoring

Regulatory body	Existing link to insurance?	Estimated cost of link to registration
General Chiropractic Council (GCC)	✓	n/a
General Dental Council (GDC)	Х	Currently looking into costs and in discussions with providers to perform automatic validation
General Medical Council (GMC)	Х	£370k to collect and collate information with no verification. Additional ongoing costs will be required
General Optical Council (GOC)	1	n/a
General Osteopathic Council (GOsC)	✓	n/a
Health Professions Council (HPC)	Х	£40K for updating registration/online renewal system to support registrants self-declarations (one off cost). Analysis or verification may be linked to ongoing CPD audits reducing ongoing expenditure
Nursing and Midwifery Council (NMC)	х	£100k - £500k for tick box exercise for 3 yearly renewals reflecting the development and implementation of this registration process only
Pharmaceutical Society of Northern Ireland (PSNI)	✓ self certification only	n/a if self certification adequate – additional specialist resource would be required to test appropriateness or adequacy at renewal estimated at £30K or £15 per registrant (additional 4% on annual fee). Further cost would be incurred if it were necessary to update information during a registration year
Royal Pharmaceutical Society of Great Britain (RPSGB)	Х	This has not been posted

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 39

70. Healthcare professional regulatory bodies may incur additional costs in monitoring compliance, which may be passed on to the individual registrants. Based on data supplied to the Independent Review Group (excluding those bodies who already have a

link to registration) and on recent registration data, the maximum estimated total cost at present is £0.91m, with an estimated minimum of £0.48m.

71. Should these costs be passed on to the registrants, the range of additional costs varies considerably due to the size of the respective healthcare professional regulatory bodies. The additional costs are estimated as follows:

**Table 8** Healthcare Professional Regulatory Body - Estimated cost per registrant of implementation of compliance monitoring

Regulatory Body	Cost 1	No of Registrants <sup>2</sup>	Cost per registrant £
GMC	£370k	246,075	£1.50
HCPC	£40k	219,228	£0.18
NMC	£100-500k	672,095	£0.15 - £0.74

Notes 1 Source: <u>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 39</u>

72. In order to produce a full Impact Assessment, respondents are invited to provide further information to test and validate these assumptions as indicated in the questions set out at Annex B.

#### To Employers

- 73. 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 healthcare professional regulatory bodies to design their own system, it is anticipated that this will place a minimal burden on employers at negligible cost.
- 74. As part of the consultation, specific questions are being asked with regard to costs and administrative burdens and respondents are invited to submit further information to test and validate these assumptions as set out at Annex B.

#### **Estimating benefits**

#### To Healthcare professionals

- 75. Healthcare professionals who are not already covered by an indemnity arrangement will benefit from the assurance that, should a negligent act cause 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.
- 76. An additional benefit is that individuals are more likley to ensure that they practise within the scope of their competence and hence their indemnity cover.

To Patients, the Public, Service Users and Tax Payers

77. In terms of Patients, the Public, Service Users and Tax Payers, they are the groups which currently 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. Pricewaterhouse Coopers, who conducted the research for the Independent Review

<sup>2.</sup> Source: CHRE Performance Review 2011-12

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.'12

#### 78. 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 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.' <sup>13</sup>

- 79. For patients and service users, as the individuals who will have suffered harm, security would be provided by the clearly delineated legal and financial responsibilities of the indemnity arrangement. In such an instance, there would also be a decrease in legal costs, but as these are a 'transfer payment', there is no overall economic benefit gained. It would however reduce distress on the parties concerned and any associated adverse publicity.
- 80. In the absence of information on the percentage of overall costs that relate to transaction costs, no correction is made to the estimate of the overall benefit to account for this.
- 81. For the tax payer, the costs that are liable to be saved are those associated with cases where there is currently no recourse to redress, such as the case cited in paragraph 9. With the provision of cover, costs which might otherwise fall to the public purse can be met from any award. There is limited data on the scale of such costs.
- 82. As part of the consultation we will be inviting respondents to submit information to validate and test these assumptions, as indicated in the questions set out in Annex B.
- To Healthcare Professional Regulatory Bodies
- 83. By taking administrative procedures (e.g. refusing to grant or renew registration) rather than fitness to practise procedures, the healthcare professional regulatory bodies will be able to deal with issues around a lack of or insufficient indemnity arrangements both quickly and at reduced expense.

<sup>&</sup>lt;sup>12</sup>Source: <u>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</u>

<sup>&</sup>lt;sup>13</sup> 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

#### To Employers

84. Employers are likely to benefit from their employees being more conscious of the limits of their scope of practice and accordingly operate within them, hence reducing adverse incidents

#### To Providers of cover

85. There will be a benefit to the providers of insurance and indemnity in terms of the increased income from premiums and the profit element that will ensue. However, there is also a counterbalancing effect of the changes, where the costs of obtaining cover are offset by the benefit received by patients in claims, thus resulting in an overall cost neutral position. Whilst it is assumed that the net present value is zero, respondents are invited to submit further data to test and validate these assumptions, with specific questions as set out at Annex B.

#### **Summary**

- 86. Based on the assumptions applied in this consultative Impact Assessment, the main costs of policy implementation will be borne by self-employed healthcare professionals who currently practise without indemnity cover, These are estimated to number 4,195, with a total cost of an estimated £1m per year. Patients will benefit through access to redress, assumed to equate to the cost of £1m, and the assurance of knowing that all practitioners are operating with cover in place.
- 87. Through the consultation respondents are invited to provide any information or data which is available to them which would help to refine the analysis above in a post consultation impact assessment to support finalised legislative proposals. As part of the consultation, we will be inviting respondents to submit information to validate and test these assumptions, as indicated in the questions set out at Annex B.

#### Cost for small firms

88. The assumed cost impact of this policy will be to individual, self-employed contractors. As set out above, we have assumed that small firms' costs may already comprise suitable liability and professional cover. We are aware that independent midwives may be particularly impacted by this. However, we are seeking further information to test and validate these assumptions as part of the consultation exercise.

#### **Equality and Human Rights**

#### Specific impact tests

**Equality Impact Assessment** 

- 89. By introduction of a requirement to hold an indemnity arrangement, there is the potential for an adverse impact upon independent midwives in that, should they be unable to obtain cover they would be unable to practise.
- 90. Whilst there are no specific protected characteristics associated with the group, there is a potential impact upon the individuals who make up the group and this is addressed in the consultation document.

91. The consultation exercise asks a specific question with regard to equalities, phrased as follows:

Q8: Do you think there are any equalities issues that would result from the implementation of the Draft Order which require consideration? If so, please provide evidence of the issue and the potential impact on people sharing the protected characteristics covered by the Equality Act 2010: disability; race; age; sex; gender reassignment; religion & belief; pregnancy and maternity and sexual orientation and carers (by association).

#### Competition

92. The options presented in this impact assessment will apply to all registered healthcare professionals. As such, we do not anticipate that they will disproportionately affect any particular group with protected characteristics.

## Summary analysis

93. The following table shows the expected costs and benefits over ten years:

Table 9: Annual profile of monetised costs and benefits of option 1

- (£m) constant (2012/13) prices

- (£III) Constant (2012/13) prices										
	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ		
	0	1	2	3	4	5	6	7	Y <sub>8</sub>	Y <sub>9</sub>
Transition costs	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	8.0	8.0	8.0	0.7
Total annual costs	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7
Transition benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Annual recurring benefits	1.0	1.0	0.9	0.9	0.9	0.8	8.0	0.8	8.0	0.7
Total annual benefits	1.0	1.0	0.9	0.9	0.9	8.0	8.0	8.0	8.0	0.7
Net present value	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

94. An estimated annual cost of £1 million will equate to total costs (discounted) of £8.6m over ten years. However, the assumption has been made that the overall costs will be balanced by benefits, giving a net present value of zero. The consultation invites respondents to provide further data to test and validate these assumptions.

## Annex A

Regulatory Bodies		No. of	Professions under the regulatory body	Indemnity Requirements			
	regulated Registrants						
General Chiropractic Council	1		Chiropractors	Required for registration by statute			
General Dental Council	7	99,518	Dentists	In Guidance. Failure to hold			
			Clinical Dental Technicians	indemnity leads to Fitness to Practise			
			Dental Hygienists	proceedings			
			Dental Nurses				
			Dental Technicians				
			Dental Therapists				
	<u> </u>	245055	Orthodontic Therapists				
General Medical Council	1	246,075	Doctors	In Guidance. Failure to hold			
				indemnity leads to Fitness to Practise			
	2	22.025	0	proceedings			
General Optical Council	2	23,935	Optometrists	Required for registration by statute			
			Dispensing Opticians (including student Opticians, student Optometrists and Optical businesses)	(not for student or businesses)			
			student Optometrists and Optical businesses)				
General Osteopathic Council	1	4,585	Osteopaths	Required for registration by statute			
General Pharmaceutical Council	2	- ,	Pharmacists	In Guidance. Failure to hold			
		12,772	Pharmacy technicians	indemnity leads to Fitness to Practise			
				proceedings			
Health Professions Council	15	3,127	Arts therapists	No Guidance			
		21,886	Biomedical Scientists				
		13,000	Chiropodists/podiatrists				
		4,679	Clinical Scientists				
		7,789	Dietitians				
		1,724	Hearing aid dispensers				
		31,928	Occupational therapists				
		10,929	Operating department practitioners				
		1,286	Orthoptists	1			
		17,935	Paramedics	1			
		46,479	Physiotherapists	1			
	Ī	894	Prosthetists/orthotists	3			
	Ī	26,533	Radiographers	3			
		13,175	Speech and Language therapists	1			
	Ī	17,864	Practitioner psychologists	1			
Nursing and Midwifery Council	2	627,535		Recommended under Code of			
- •	Ī	44,560	Midwives	Conduct			
Pharmaceutical Society of Northern	1	2,098	Pharmacists in Northern Ireland	In Guidance. Failure to hold			
Ireland	Ī			indemnity leads to Fitness to Practise			

**Annex B** Consultation questions inviting respondents to supply additional information to test and validate assumptions

Q6: Please provide any information with regard to the potential barriers to independent midwives moving to alternative governance and delivery practices in order to obtain appropriate indemnity arrangements.

Q9: Please provide comments as to the accuracy of the costs and benefits assessment of the proposed changes as set out in the Impact Assessment (including, if possible, the provision of data to support your comments).

Q10: Please provide information on the numbers of self employed registered healthcare professionals and whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance.

Q11: Please provide information on the numbers of employed healthcare professionals who, in addition to working in an employed capacity covered by an employer's arrangement for indemnity or insurance, undertake self-employed practice. Where possible, please provide information as to whether they are in possession of indemnity cover or business insurance which includes public liability insurance and professional indemnity insurance for that self -employed element of their practice.

Q12: Do you have views or evidence as to the likely effect on costs or the administrative burden of the proposed changes set out in the Draft Order? Please provide information/examples in support of your comments.

Q13: Do you think there are any benefits that are not already discussed relating to the proposed changes?

Please provide information/examples in support of your comments.

Regulatory Bodies	Professions	No. of	Professions under the regulatory body	Indemnity Requirements
	regulated	Registrants		
General Chiropractic Council	1	2,700	Chiropractors	Required for registration by statute
General Dental Council	7	99,518	Dentists Clinical Dental Technicians Dental Hygienists Dental Nurses Dental Technicians	In Guidance. Failure to hold indemnity leads to Fitness to Practise proceedings
			Dental Therapists Orthodontic Therapists	
General Medical Council	1	246,075	Doctors	In Guidance. Failure to hold indemnity leads to Fitness to Practise proceedings
General Optical Council	2	23,935	Optometrists Dispensing Opticians (including student Opticians, student Optometrists and Optical businesses)	Required for registration by statute (not for student or businesses)
General Osteopathic Council	1	4,585	Osteopaths	Required for registration by statute
General Pharmaceutical Council	2		Pharmacists	In Guidance. Failure to hold
			Pharmacy technicians	indemnity leads to Fitness to Practise proceedings
Health Professions Council	15	3,127	Arts therapists	No Guidance
		21,886	Biomedical Scientists	1
		13,000	Chiropodists/podiatrists	1
		4,679	Clinical Scientists	1
		7,789	Dietitians	1
		1,724	Hearing aid dispensers	1
			Occupational therapists	1
			Operating department practitioners	1
			Orthoptists	1
			Paramedics	1
			Physiotherapists	1
			Prosthetists/orthotists	1
			Radiographers	1
			Speech and Language therapists	1
			Practitioner psychologists	1
Nursing and Midwifery Council	2	627,535		Recommended under Code of
and many country			Midwives	Conduct
Pharmaceutical Society of Northern Ireland	1		Pharmacists in Northern Ireland	In Guidance. Failure to hold indemnity leads to Fitness to Practise proceedings

Number of groups not currently required to hold indemnity arrangements

Regulatory Bodies	Professions	No. of	Professions under the regulatory body	Indemnity Requirements
	regulated	Registrants		
Health Professions Council	15	3,127	Arts therapists	No Guidance
		21,886	Biomedical Scientists	
		13,000	Chiropodists/podiatrists	
		4,679	Clinical Scientists	
		7,789	Dietitians	
		1,724	Hearing aid dispensers	
		31,928	Occupational therapists	
		10,929	Operating department practitioners	
		1,286	Orthoptists	
		17,935	Paramedics	
		46,479	Physiotherapists	
		894	Prosthetists/orthotists	
		26,533	Radiographers	
		13,175	Speech and Language therapists	
		17,864	Practitioner psychologists	
Nursing and Midwifery Council	2	627,535	Nurses and Midwives	Recommended under Code of
		44,560	Midwives	Conduct

Source: CHRE Performance Review 2011-12 http://www.chre.org.uk/satellite/402

Regulatory Bodies	Professions regulated <sup>1</sup>	No. of Registrants <sup>1</sup>	Professions under the regulatory body <sup>1</sup>	Professional Body	No of members	Professional Indemnity Provided	Cost of membership
General Chiropractic Council	1	2,700	Chiropractors	British Chiropractic Association	At least 1325	Yes, level not provided	?
			Dentists	British Dental Association	23,000	Yes, through	£546
			Cilincal Dental	British Association of Clinical Dental Technology	?	Lloyd & Whyte ?	£862.50
			Dental Hygienists	British Society of Dental Hygiene and Therapy	4000+	Yes, through	£92.50
General Dental	7	00.510	Dental Nurses	British Association of Dental Nurses	2	Lloyd & Whyte Yes, level not	£85.91
Council	/	99,518	Dental Technicians	The Dental Technologists Association	2	provided Yes, £3m	£94
			Dental Therapists	British Society of Dental Hygiene and Therapy	4000+	Yes, through	£92.50
			Dentai Therapists	The Orthodontic National Group for Dental Nurses & Orthodontic	4000+	Lloyd & Whyte	272.30
			Orthodontic Therapists	Therapists	?	?	£25
General Medical Council	1	246,075	Doctors	British Medical Association	141,000	?	Free until 30/09/12
Council				College of Optometrists	13,000	No	£293.73
			Optometrists	Association of Optometrists	10,000	Yes, £2m	£595
General Optical	2	22.025		Association of British Dispensing Opticians			
Council	2	23,935	Dispensing Opticians (including student Opticians, student Optometrists and Optical businesses)		5,600	?	?
C				Federation of (Opthalmic and Dispensing) Opticians		Yes £5m	?
General Osteopathic Council	1	4,585	Osteopaths	British Osteopathic Association	?	Yes, £10m	£220
General	2	43,756 pharmacists	Pharmacists	Royal Pharmaceutical Society	?	No	£192
Pharmaceutical Council	2	12,772 pharmacy technicians	Pharmacy technicians	Association of Pharmacy Technicians	?	Yes	£35 + £10 initial
		3,127	Arts therapists	British Association of Art Therapists British Association of Dramatherapists  British Association for Music Therapy	?	No, but reduced cost through membership ?	£80
		21,886	Biomedical Scientists	Institute of Biomedical Science	? 19,000	Yes, corporate members	£160 £152
		13,000	Chiropodists/podiatrists	The Society of Chiropodists & Podiatrists The British Chiropody & Podiatry Association The Institute of Chiropodists & Podiatrists The Alliance of Private Sector Chiropody and Podiatry	7,000	Yes, £5m Yes, £5m	£1,860 £215 £223 + £105 registration fee ?
					?	Yes, £6m	
				Association of Clinical Scientists	?	?	£265
Health Professions		7,789	Dietitians Hearing aid dispensers	British Dietetic Association  British Society of Hearing Aid Audiologists	5100 1,200	Yes, £3m No	£265 £185
Council	15	31,928		British Association of Occupational Therapists		Yes, £5m	£256
		10,929	Operating department practitioners	College of Operating Department Practitioners Association for Perioperative Practice PROPRIUS		Yes, £1m Yes, £3m	£ 60.00 £102
		1,286	Orthoptists	British Orthoptic Society	1150	Yes for self employed or private work carried out by employees of other bodies £2m	£335
				College of Paramedics	?	?	£50
		46,479 894	Physiotherapists Prosthetists/orthotists	Chartered Society of Physiotherapy British Association of Prosthetists & Orthotists		Yes, £10m Yes, £5m	£311 £360
		26,533		The Society & College of Radiographers		Yes, £5m	£243
		13,175	Speech and Language	Royal College of Speech and Language Therapists		Yes, £5m	£208
		·	Practitioner psychologists	British Psychological Society  Association of Educational Psychologists		Up to £5m	£119
				· · · · · ·	?	?	£225
Nursing and Midwifery Council	2	672,095	Nurses Midwives	Royal College of Nursing Royal College of Midwives	410,000 Vast Majority	Yes Yes, £3m	£195 £239
Pnarmaceuticai		2.0==	Pharmacists in Northern		Assuming	2 00, 20111	13/2+
Society of Northern	1	2,098	Ireland	Pharmaceutical Society of Northern Ireland	2,650 as it's	ı	registration fee

<sup>1</sup> Source: CHRE Performance Review 2011-12 http://www.chre.org.uk/satellite/402 2 HCPC website 3 Professional Body website

Annual Population Survey (APS), Jan - Dec 2010					Thousands,	not seasonally adjuste
				UK		
		Private			Public	
2. PROFESSIONAL OCCUPATIONS	ALL	Employee	Self Employed	ALL	Employee	Self Employed
221. HEALTH PROFESSIONALS						
MEDICAL PRACTITIONERS	64	12	51	17	9 179	
PSYCHOLOGISTS	6	1	5	2	4 24	
PHARMACISTS & PHARMACOLOGISTS	29	19	10	1	3 13	
OPHTHALMIC OPTICIANS	12	8	4		1 1	
DENTAL PRACTITIONERS	26	1	25		9 9	
SOCIAL WORKERS	21	15	6	g	8 98	
3. ASSOCIATE PROFESSIONAL AND TECHNICAL	_				-	
321, HEALTH ASSOCIATE PROFESSIONALS						
NURSES	83	80	3	42	6 426	
MIDWIVES	1	1	-	3		
PARAMEDICS	*	*	-	2		
MEDICAL RADIOGRAPHERS	4	4	-	2		
CHIROPODISTS	6	-	6		5 5	
DISPENSING OPTICIANS	6	5	1		-	
PHARMACEUTICAL DISPENSERS	33	32	1	1	3 13	
MEDICAL AND DENTAL TECHNICIANS	19	14	5	2	4 24	
322. THERAPISTS						
PHYSIOTHERAPISTS	14	5	9	3	2 32	
OCCUPATIONAL THERAPISTS	3	2	1	3	0 30	
SPEECH AND LANGUAGE THERAPISTS	2	1	1	1	2 12	
THERAPISTS NEC 1	48	8	39	2	1 21	
6. PERSONAL SERVICE OCCUPATIONS						
611. HEALTH CARE & RELATED PERSONAL SERVICES						
DENTAL NURSES	34	34	-	1	2 12	
TOTAL	411	242	167	97	4 974	
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 chirppodists 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.

		UK							
		Private				Public			
PROFESSIONAL GROUP	ALL	ALL Employee Self Employed			ALL	Employee	Self Employed		
PSYCHOLOGISTS	6	1	5		24	24	-		
NURSES	83	80	3		426	426			
CHIROPODISTS	6	-	6		34	34			
PHYSIOTHERAPISTS	14	5	9		21	21			
OCCUPATIONAL THERAPISTS	3	2	1		20	20			
SPEECH AND LANGUAGE THERAPISTS	2	1	1		5	5			
THERAPISTS NEC BASED ON REGULATOR DATA 1	15	2	12		38	38			
	129	91	37		530	530			
TOTAL SELF EMPLOYED NOT REQUIRED TO HOLD INSURANCE/INDEMNITY <sup>2</sup>	-	-	37						

Source: Labour Market Survey and Regulatory Body data

- Therapists not elsewhere classified includes the following professional groups: Arts Therapists, Biomedical Scientists, Clinical Scientists, Dieticians, Operating Department Practitioners, Orthoptists and Prosthetists/Orthotists. Split based on ONS ratios
   Estimate of the total number of professionals not required by statute or code of conduct to hold insurance or indemnity.

CHIROPRACTORS	2.4	.4	2.0		
OSTEOPATHS	4.0	.7	3.3		

REGISTRANT DATA FOR THERAPISTS NEC EXC. OSTEOPATHS AND CHIROPRACTORS

52,314

Split of Therapists NEC by ONS ratios	Total	employee (public)		Employee private	self employed
ONS Data		69	21	8	39
Ratio	10	0%	30%	12%	57%
				17%	83%
Regulator Data, based on ONS ratio		52	16	6	30
Regulator data based on estimated NHS employment, with private sector employee/self employed on ONS					
ratios		52	38	2	12

Therapists NEC as per HCPC registration

Regulatory Bodies	No. of Registrants	Professions under the regulatory body	Estimated proportion working outside the	Estimated proporti outside the NHS, calculation	mid point
General Chiropractic Council	2700				
			75-100%	87.5%	2,363
General Osteopathic Council	4585				
			75-100%	87.5%	4,012
Health and Care Professions Council	3,127	Arts therapists	75-100%	87.5%	2,736
	21,886	Biomedical Scientists	0-10%	5%	1,094
	4,679	Clinical Scientists	0-10%	5%	234
	7,789	Dietitians	10-75%	42.5%	3,310
	1,724	Hearing aid dispensers	100%	100%	1,724
	10,929	Operating department practitione	10-75%	42.5%	4,645
	1,286	Orthoptists	10-75%	42.5%	547
	894	Prosthetists/orthotists	10-75%	42.5%	380
Total	52,314				14,670

Estimated Proportion source: Independent Review Group report Annex B, page 32 All Hearing Aid Dispensers regulated under the HCPC are employed in the private sector

Profession	Number of Registrants	Number registered with professional body offering IA (excluding professional bodies where membership is currently unknown)	membership (assumed 100%	Cost of professional body membership	Extent of IA
Psychologists	17,864	45,254	100 /6		£5m
Nurses	627,535	410,000		2100	?
Midwives	44,560	Vast majority		LZSS	£3m
Paramedics	17,935	?	n/a	200	?
Medical Radiographers	26,533	21,541		LZTJ	£5m
Chiropodists	13,000	17,000		21000, 2210	£5m
Physiotherapists	46,479	51,250		2011	£10m
Occupational Therapists	31,928	29,000	91%	£256	£5m
Speech and Language Therapists	13,175	14,000	100%	£208	£5m
Therapists not classified elsewhere (exc. chiropractors and osteopaths)	52,314 891,323		75%		Up to £5m

Source: DH trawl of regulator and professional body data

Note: Professional Body membership may exceed registrant numbers where professional bodies cover wider groups than regulated health professionals, registrants hold membership of more than one professional body or individuals remain as members of professional bodies after withdrawal from a professional register.

No data on IA available for Arts Therapists, Clinical Scientists, Hearing Aid Dispensers, Orthoptists, and Prosthetists. Includes Operating Department practitioners registered with two professional bodies (5000 and 7000).

Professions with estimated professional body membership of less than 100%:

Profession	Number of self-employed, private sector practitioners, with therapists based on professional body/regulator data, mid point calculation	Estimated % of self- employed practitioners covered via 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	Individual cost of professional body membership	Total estimated cost impact of professional body membership for professionals affected by the proposed new requirement
Nurses	3,000	65%		£195	£203,000
Occupational Therapists	1,000	91%		£256	
Therapists not classified	12,173				
elsewhere (exc.	, i				
chiropractors and					
osteopaths)		75%	0,000	£255	
TOTAL	16,173	1	4,195	£240	£1,006,000

## **Indemnity Legislation**

Costs and benefits spreadsheet Rob Stones, July 2012

## **Central Assumptions**

	Best estimate	Low	High	Source	Notes
Approx number of registrants impacted	4,195				
Unit cost of indemnity	£ 240				
cover					

£ 1,006,000

#### Summary of costs and benefits and comparison of each optior

Option 2
Description: Mandating indemnity cover as a requirement of registration

Price Base Year	PV Base Year	Period	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:
2012/13	2012/13	10			0.0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	(Present Value)	
Low				
High				
Best Estimate		1.0		8.6

BENEFITS (£m)	Total Transition (Constant Price) Years		Annual (excl. Transition) (Constant	(Present Value)	
Low			Price)		
High					
Best Estimate			1.0		8.0
Key assumptions/sensitiv	ities/risks Di	scount rate (	%)		3.5%

#### Annual profile of monetised costs and benefits of preferred option - (£m) constant (2012/13) prices

•	(, (, () p () p											
	$Y_0$	<b>Y</b> <sub>1</sub>	Y <sub>2</sub>	Y <sub>3</sub>	Y <sub>4</sub>	Y <sub>5</sub>	Y <sub>6</sub>	Y <sub>7</sub>	Y <sub>8</sub>	Yg		
Transition costs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
Annual recurring	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7		
Total annual costs	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7		
Transition benefits	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
Annual recurring benefits	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7		
Total annual benefits	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.7		
Net present value	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		

8.6

8.6 0.0





Health Care and Associated Professions (Indemnity Cover) Order 2013

**Equality Analysis** 

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# Health Care and Associated Professions (Indemnity Cover) Order 2013

# **Equality analysis**

Prepared by the Equality and Inclusion Team, Department of Health

## Introduction

The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
- Advance equality of opportunity between people who share a protected characteristic and those who do not.
- Foster good relations between people who share a protected characteristic and those who do not.

The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty. This analysis sets out the Department's view on how the proposed Order meets the duties.

# **Equality analysis**

Title: Health Care and Associated Professions (Indemnity Cover) Order 2013

Relevant line in DH Business Plan 2011-2015:

2.8. Promote safe, effective and respectful care by health and social care professionals, through implementation of the professional regulation Command Paper, "Enabling Excellence"

#### What are the intended outcomes of this work?

Where harm has been caused through negligence on the part of a healthcare professional, patients, the public or service uses should have means of redress.

The intended effect is to require all healthcare professionals to have an indemnity arrangement in place (either arranged personally or in place as a result of their employment status). Unless healthcare professionals can demonstrate that such arrangements are in place they will be unable to register as a healthcare professional and so be unable to practise.

Who will be affected? e.g. staff, patients, service users etc

Registered health professionals

**Patients** 

Service Users

**Evidence** The Government's commitment to transparency requires public bodies to be open about the information on which they base their decisions and the results. You must understand your responsibilities under the transparency agenda before completing this section of the assessment. For more information, see the current <u>DH Transparency Plan</u>.

What evidence have you considered? List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template.

Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional.

No specific examination of equality issues but work of the review was undertaken in the context of existing equalities duties.

Details are contained here:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH\_117454

Ongoing discussions with Regulatory Bodies and key stakeholders

Whilst no equality issues have been identified, additional information will be sought through Consultation exercise to confirm position.

**Disability** Consider and detail (including the source of any evidence) on attitudinal, physical and social barriers. We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Sex** Consider and detail (including the source of any evidence) on men and women (potential to link to carers below). We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Race** Consider and detail (including the source of any evidence) on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.

We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Age** Consider and detail (including the source of any evidence) across age ranges on old and younger people. This can include safeguarding, consent and child welfare.

We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Gender reassignment (including transgender)** Consider and detail (including the source of any evidence) on transgender and transsexual people. This can include issues such as privacy of data and harassment. We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Sexual orientation** Consider and detail (including the source of any evidence) on heterosexual people as well as lesbian, gay and bi-sexual people.

We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Religion or belief** Consider and detail (including the source of any evidence) on people with different religions, beliefs or no belief.

We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Pregnancy and maternity** Consider and detail (including the source of any evidence) on working arrangements, part-time working, infant caring responsibilities.

There is the potential for minor negative impact on pregnant women wishing to retain the services of an independent midwife, should individual registrants be forced out of business. However the reported number of midwives practising independently is 170 (source NMC) and the assumption is that the majority of these will be able to obtain cover as part of a Social Enterprise Company or similar schemes. On this basis, the impact is deemed to be minor. The consultation asks a specific question with regard to this assumption.

Q6: Please provide any information with regard to the assumption that the majority of independent midwives will be able to obtain cover through Social Enterprise Companies or similar schemes.

**Carers** Consider and detail (including the source of any evidence) on part-time working, shift-patterns, general caring responsibilities.

We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

**Other identified groups** Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.

We have been unable to identify any evidence that these individuals may experience a negative impact or discrimination as a result of the proposal.

## **Engagement and involvement**

Was this work subject to the requirements of the cross-government <u>Code of Practice on Consultation?</u> (Y/N) Y

How have you engaged stakeholders in gathering evidence or testing the evidence available? The Independent Review Group commissioned independent research carried out by Pricewaterhouse Cooper to establish the scale of impact.

How have you engaged stakeholders in testing the policy or programme proposals? The IRG comprised representatives from key stakeholders, including regulatory bodies and patient and public representatives.

Stakeholders

Additionally direct research into public perceptions and reactions was commissioned.

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

Details are contained here:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH\_117454

**Summary of Analysis** Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.

Whilst the work of the IRG was undertaken in the context of the equalities duties extant at the time, no specific issue were identified. Accordingly, the consultation exercise will seek to gather further evidence of equalities issues that may arise from the implementation of the legislation.

Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups.

Eliminate discrimination, harassment and victimisation Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).

There is no evidence on this to suggest a particular group would be affected by the proposed policy.

Advance equality of opportunity Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).

There is no evidence on this to suggest a particular group would be affected by the proposed policy.

**Promote good relations between groups** Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).

What is the overall impact? Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?

**Addressing the impact on equalities** Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.

Action planning for improvement Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.

The consultation exercise is calling for any additional information respondents may have to assist in refining existing data.

Specific questions included in the consultation will call for any evidence of the potential to impact on any group with protected characteristics

Analysis of consultation responses will help refine EQIA for publication of final Order

Q8: Do you think there are any equalities issues that would result from the implementation of the Draft Order which require consideration? If so, please provide evidence of the issue and the potential impact on people sharing the protected characteristics covered by the Equality Act 2010: disability; race; age; sex; gender reassignment; religion & belief; pregnancy and maternity and sexual orientation and carers (by association).

#### For the record

Name of person who carried out this assessment:

Mike Lewis

Date assessment completed:

8/10/12

Name of responsible Director/Director General:

Gavin Larner

Date assessment was signed:

# **Action plan template**

This part of the template is to help you develop your action plan. You might want to change the categories in the first column to reflect the actions needed for your policy.

Category	Actions	Target date	Person responsible and their Directorate
Consultation	Consultation exercise to include specific question on equalities issues arising from implementation of legislation.		
Analysis of evidence and assessment	Analysis of responses will allow assessment of impact and where necessary, amendments will be made to the Order.		
Monitoring, evaluating and reviewing	The Government has asked the Law Commissions for England and Wales, Scotland and Northern Ireland to review the legislative framework for the regulation of health professions across the UK and social workers in England. This Order will be considered as part of that review.		
Transparency (including publication)	This EQIA will be published as part of the consultation exercise and, following analysis of responses, an amended version will be published alongside the final Order.		