



Health Care and Associated Professions (Indemnity Arrangements) Order 2013

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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Health Care and Associated Professions (Indemnity Arrangements) Order 2013

A paper for consultation

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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 efficient 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.

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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

¹ 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.

² 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.

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

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)³. 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 regulated⁴. 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:

³ [Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare](#)

⁴ 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.'⁵

⁵ [Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010](#) page 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.⁶
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.'⁷
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.⁸

⁶ [Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response: DH, 2010](#) page 14

⁷ [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

⁸ [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 2010⁹, 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)¹⁰ 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

⁹ [Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional - Government response](#), DOH 2010

¹⁰ [Enabling Excellence: Autonomy and Accountability for Health and Social Care Staff](#) DH 2011, p20

regulatory bodies¹¹ 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.

¹¹ Nursing and Midwifery Council and the Health and Care Professions Council

¹² [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

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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 midwives¹³. Whilst these individuals have historically been unable to obtain individual indemnity or insurance cover, independent research¹⁴, 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.

¹³ Local Supervising Authority data, NMC 2012

¹⁴ 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:

- 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: hrdlistening@dh.gsi.gov.uk
- 5 You may also complete the online consultation response document at <http://consultations.dh.gov.uk>
- 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:
www.dh.gov.uk/en/FreedomOfInformation/DH_088010
- 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

Health Care and Associated Professions (Indemnity Arrangements) Order 2013

Annex A Regulatory Bodies, professions and Indemnity requirements

Regulatory Bodies	Professions regulated	No. of Registrants	Professions under the regulatory body	Indemnity Requirements
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 Dental Therapists Orthodontic Therapists	In Guidance. Failure to hold indemnity leads to Fitness to Practise proceedings
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	43,756	Pharmacists	In Guidance. Failure to hold indemnity leads to Fitness to Practise proceedings
		12,772	Pharmacy technicians	
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	Recommended under Code of Conduct
		44,560	Midwives	
Pharmaceutical Society of Northern Ireland	1	2,098	Pharmacists in Northern Ireland	In Guidance. Failure to hold 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.