**EXPLANATORY MEMORANDUM TO**

**THE HEALTH CARE AND ASSOCIATED PROFESSIONS (INDEMNITY ARRANGEMENTS) ORDER 2014**

**2014 No. [XXXX]**

**1.** This explanatory memorandum has been prepared by The Department of Health and is laid before Parliament by Command of Her Majesty. This Order is being laid simultaneously before the Scottish Parliament.

## 2. Purpose of the instrument

2.1 This Order amends the framework legislation in respect of regulated healthcare professionals to require regulated healthcare professionals who are practising to have indemnity or insurance cover which provides appropriate cover in respect of the risks that may arise in the course of their work to ensure that patients are able to claim compensation they may be entitled to.

## 3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

## 4. Legislative Context

4.1 This Order implements the main recommendations of the Finlay Scott Review[1](see Annex 1) and Article 4(2)(d) of the Directives2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare ("the Directive") which requires Member States to have in place systems of professional liability insurance or similar arrangements in respect of health care treatment provided in that Member State.

4.2 The key recommendation of the Finlay Scott Review is:

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

4.3 This Order amends the framework legislation governing each of each of the regulated healthcare professionals. The amendments revise existing provisions on indemnity or insurance cover, and in the case of the Nursing and Midwifery Council and the Health and Care Professions Council inserts new provisions on indemnity and insurance cover. The key provision imposes an obligation on practising regulated healthcare professionals to have appropriate cover in place in respect of the risks that may be incurred in carrying out their work. Regulated in this context refers to those healthcare professionals such as

[1] Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional – June 2010. A copy of the review may be obtained by writing to the Professional Standards Division, Room 2N09, Quarry House, Quarry Hill, Leeds LS2 7UE.

medical practitioners who have to register with a regulatory body such as the General Medical Council. The legislation also allows a regulatory body to remove or refuse a person's entry on to the register if there is a failure to comply with the obligation to have appropriate cover; and in more serious cases, the matter may be dealt with via fitness to practise procedures.

4.4 The changes to the legislation governing each of the regulatory bodies also satisfy the requirements of Article 4(2)(d) of the Directive, namely that the Member State of treatment shall ensure that:

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

4.5 A copy of the transposition note can be found at Annex 2.

4.6 The majority of the Directive has been implemented by the National Health Service (Cross-Border Healthcare) Regulations 2013 (S.I. 2012/2269) in relation to England and Wales; the National Health Service (Cross-Border Healthcare)(Scotland) 2013 (S.S.I 2013/ 292) in relation to Scotland, and The Health Services (Cross-Border Healthcare) Regulations (Northern Ireland) 2013 (S.R. 299) in relation to Northern Ireland, which has also implemented Article 4(2)(d) in relation to regulation of pharmacy in Northern Ireland[2]

*Scrutiny History*

**Domestic concerns on lack of indemnity cover for regulated healthcare professionals**

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

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

4.9 There are 32 groups of regulated healthcare professionals (the health care professionals). All must be registered by the appropriate statutory healthcare professional regulatory bodies in order to practise their profession, medical

[2] The statutory regulation of the health professions is fully devolved to NI as part of the devolution settlement, but in practice (with the exception of pharmacy) there has been an agreement that the regulation of the health professions is mutually beneficial if done on a UK wide basis. NI has a separate regulatory body for pharmacy, the Pharmaceutical Society of NI

practitioners must also obtain a licence to practise. There is currently no consistency across the health care professional regulatory bodies with regard to legislation or guidance on the need for individual regulated health care professionals to hold insurance or indemnity cover (an indemnity arrangement).

4.10 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 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 there are statutory provisions on the same but 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, and for which there is no is it a statutory 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 in their code[3].

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

4.12 Given the issues of consistency across the regulated healthcare professionals, and the lack of redress in some cases, in 2010 the Government accepted the recommendations of the independent Finlay Scott review and gave a commitment to implement an indemnity requirement in light of the final wording of the Patient's Directive. This policy was adopted by the subsequent government

4.13 The Review Group had been aware of a draft EU Directive on cross-border healthcare and was satisfied that none of the conclusions or recommendations in its report ran counter to the principles of the draft Directive. Therefore the Government welcomed the EU Directive when it was passed.

4.14 The Department is aware that there continues to be cases outside of the NHS where indemnity cover has not been in place and any attempt by the patient to seek redress in court would not have resulted in compensation to the patient due to the lack of personal assets. To address this the Government is committed to ensuring that patients have recourse to compensation where they suffer harm though negligence on the part of a regulated practising healthcare professional.

[3] NMC - The code: Standards of conduct, performance and ethics for nurses and midwives

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

4.15 Following negotiations across Europe, the European Union Commission, Parliament and European Council formally adopted Directive 2011/24/EU on the application of patients' rights in cross-border health care (the Directive), via the co-decision process where all 3 institutions have to agree to the measure before it can be adopted. Member States had until 25 October 2013 to transpose the Directive's requirements into their national laws and the UK is currently at serious risk of infraction proceedings for failure to implement fully. As noted above in paragraph 4.5 the directive has been implemented, save for Article 4(2)(d).

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

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

4.17 In its definitions, the Directive sets out that:

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

And that:

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

4.18 These provisions do not apply in relation to healthcare professionals established in another Member State, who provide services on a temporary and occasional basis in another Member State. Article 6(a) (exemptions) of Directive 2005/36/EU on the recognition of professional qualifications, provides that a host Member State shall exempt such service providers from the requirements it places on professionals established in its territory relating to registration with a professional organisation or body. However, under Article 7.1 Member States can require, in advance of the provision of services, a written declaration including details of insurance cover or other means of personal and collective protection.

## 5. Territorial Extent and Application

5.1 This instrument extends to all of the United Kingdom but where it makes amendments to other legislation that only applies to a part of the United Kingdom the amendments have the same extent as the legislation being amended.

## 6. European Convention on Human Rights

Daniel Poulter MP, the Parliamentary Under-Secretary of State at the Department of Health, responsible for this legislation, has made the following statement regarding Human Rights:

"In my view the provisions of the Health Care and Associated Professions (Indemnity Arrangements) Order 2014 are compatible with the Convention rights."

## 7. Policy background

*What is being done and why*

7.1 This Order implements the Finlay Scott review recommendations and Article 4(2)(d) of Directive 2011/24/EC of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare ("the Directive").

7.2 The four UK Health Departments accepted the recommendations of the Finlay Scott review which recommended that all regulated healthcare professionals should be required to hold insurance or indemnity as a condition of their registration (and in the case of medical practitioners, a licence to practise) when carrying out work as a regulated healthcare professional. We have therefore been committed to requiring all regulated healthcare professionals to hold indemnity or insurance for some time. The EU Directive reinforces the direction of travel and commits us to legislation.

7.3 The purpose of the policy is to ensure that people have access to appropriate redress in the unlikely event that they are negligently harmed during the course of their care. Everyone should have this by right, and the overwhelming majority of regulated healthcare professionals will be unaffected by the proposals because they are already indemnified through personal cover or cover provided by their employers.

7.4 This order makes provision that all practising regulated healthcare professionals to hold an insurance or indemnity arrangement as a condition of their registration (and in the case of medical practitioners, a licence to practise) with the relevant regulatory body.

7.5 It should be noted that:

- The vast majority of regulated healthcare professionals are in receipt of cover by virtue of their employer's liability, or via a professional body which offers an indemnity arrangement as a benefit of membership.

- It will be for individual healthcare professionals to assure themselves that appropriate cover is in place for all the work they undertake. Unless healthcare professionals who are or intend to practise can demonstrate to the satisfaction of the regulatory bodies that such arrangements are (or will be) in place they will be unable to be registered as a healthcare professional and so will be unable to practise.

## 8. Consultation outcome

8.1 A public consultation exercise took place between 22 February 2013 and 17 May 2013 and was made available on the Department of Health website for that period.

8.2 The consultation asked for views on the requirement for all practising regulated healthcare professionals to hold an insurance or indemnity arrangement as a condition of their registration with the relevant regulatory body.

8.3 We have received 816 responses putting forward a variety of views about the proposed legislation. However a small number of independent midwives (self-employed midwifes and working in the private sector) are affected by these proposal and therefore have expressed their concerns in strong terms in their response to the consultation. Their main concern is about their ability to obtain affordable indemnity arrangements. The Department recognises that the new requirements may require midwives to change their own governance and delivery practices to comply with an indemnity policy. It is for the individual practitioner themselves to determine a suitable operating model under which they are able to continue to practice. We are aware of midwives practising in the private sector, as part of a corporate structure, who have obtained cover that will enable them to provide care in an independent way, either commissioned by the NHS or by private clients.

8.4 Whilst we acknowledge the issues raised by individuals and select groups who disagree with the proposals, those in agreement with this proposals were mainly professional regulators and other membership organisations who were responding on behalf of their membership. They recognised that for the vast majority of statutorily regulated healthcare professionals, who are practising, the new legislation will mean no change. Therefore, after careful consideration of the responses to the Department is of the view that as the vast majority of regulated healthcare professionals are in receipt of cover by virtue of their employer's liability, or via a professional body which offers an indemnity arrangement as a benefit of membership the benefits brought about by the new legislation outweigh any negative impact that might arise from the proposals.

8.5 The impacts and equality considerations that have been raised through this consultation process have been considered fully as part of the Impact Assessment and Equalities Impact Assessment and will be made available when the Order when it is laid in Parliament.

8.6 Following consultation, the Department is of the view that the benefits brought about by the new legislation outweigh anything negative that might arise from the proposals.

8.7 The full consultation analysis can be accessed via the following web address: https://www.gov.uk/government/consultations/protecting-patients-from-negligence

## 9. Guidance

9.1 This Order amends primary legislation for of the eight regulatory bodies. The provisions contain powers which enable the regulatory bodies to make rules, for example, on the information it requires to determine if there is appropriate cover in place at registration. They will provide guidance to their registrants on the provisions set out in the Order. The Department of Health does not intend to issue guidance.

## 10. Impact

10.1 The impact on business is small:

- The cost to health professionals of insurance premiums, excluding midwives, we estimate an annual cost to about 4,200 practitioners of £0.9m.
- For independent midwives, we estimate an annual cost to around 150 practitioners of £2.0m. There is a cost to set up social enterprises for independent midwives to employ health professionals so that they will be able to obtain insurance (estimated cost of £1.5m over 2 years).
- Combined, these cost give an annual net cost to business of £2.0m.

10.2 The cost to regulatory bodies (which are not considered as businesses or civil society organisations) of implementing checks (estimated transition cost of £716k, with annual recurring costs (in each of the 10 years) of £80k).

10.3 Patients who bear the cost of adverse events both in terms of cost and personal impact will benefit from new liability arrangement's in place. They will have access to redress for any harm they have suffered from the healthcare they have received. The full benefits accrue to these patients.

10.4 We do not expect there to be any negative impact on the public sector, we expect it to benefit from reduced costs to the public purse of meeting certain longer term care and support services that are provided on a means-tested basis for patients following adverse incidents due to the negligent action of health care professionals who do not have an indemnity arrangement in place.

10.5 A full Impact Assessment has been completed and can be access via the following web address:
https://www.gov.uk/government/consultations/protecting-patients-from-negligence
This received a green rating from the Regulatory Policy Committee.

## 11. Regulating small business

11.1 The legislation does not directly apply to small business, the changes that it brings about relate to the individual rather than business.

## 12. Monitoring & review

12.1 The Commission are required to report on the operation of the Directive by 25 October 2015 and then every three years thereafter. The Department of Health and the Regulatory Bodies will jointly monitor, on an ongoing basis, the operation of the legislation, including how it works in practice.

## 13. Contact

Sarah McKenzie**,** at the Department of Health Tel: 0113 2546120 or email: sarah.mkenzie@dh.gsi.gov.uk can answer any queries regarding the instrument.

**Annex 1**

**Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional – June 2010 (also known as the Finlay Scott review)**

1. The Finlay Scott Review examined whether making insurance or indemnity a condition of registration is the most cost effective and proportionate means of achieving the policy objective that all registered healthcare professionals must have cover. The aim being that when harm has been caused through negligence on the part of a registered healthcare professional, those affected should receive any redress to which they are entitled.

2. The main conclusion of the review was that a statutory condition of registration is the most cost effective and proportionate means of achieving the policy objective. They set out that :
"a condition of registration would add significant value – it would apply equally and unequivocally to all registered healthcare professionals; would be seen by patient and the public to do so; and would enhance patient and public confidence. In addition, it would reduce enforcement costs compared with alternatives, without increasing compliance costs or the cost of compliance testing."

3. The four UK Health Administrations welcomed the report and responded jointly accepting the recommendations. Together they committed to ensuring that legislative changes be introduced at the next most appropriate opportunity to give effect to the recommendations.

4. This was considered in light of the changes brought about by the Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-Border Healthcare resulting in the development of the Order we are now laying in Parliament.

**Annex 2**

**Directive 2011/24/EU of the European Parliament and of the Council of 9th March 2011 on the application of patient rights in cross- border healthcare.**

1. Article 4(2)(d) of Directive 2011/24/EU of the European Parliament and of the Council on the application of patient's rights in cross-border healthcare ("the Directive") is transposed by The Health Care and Associated Professions (Indemnity Arrangements) Order 2014.

2. This will be transposed by separate measures in relation to the Pharmaceutical Society of Northern Ireland.

3. The UK government was required to transpose the Directive by 25th October 2013.

| Article of Directive | Subject Matter | Implementation |
|---|---|---|
| Article 4(2)(d) | Article 4(2)(d) requires member states to ensure systems of professional liability insurance or equivalent provision. | Transposed by the Health Care and Associated Professions (Indemnity Arrangements) Order 2014 |