



Department  
of Health &  
Social Care

# **Appropriate clinical negligence cover**

**A consultation on appropriate clinical negligence cover  
for regulated healthcare professionals and  
strengthening patient recourse**

Published 6 December 2018

Updated 8 February 2019

# Contents

Executive summary .....	3
1. Introduction .....	7
2. Policy background .....	10
3. Clinical negligence cover.....	14
4. Policy objectives and concerns .....	18
5. Policy options .....	25
6. Consultation questions .....	34
7. Responding to the consultation .....	36
Annex A: Healthcare professional regulatory bodies and current definitions of appropriate cover.....	38
Annex B: Summary of impact of the consultation options .....	41
Annex C: Equality Act - Section 149 .....	45
Glossary.....	47
References .....	50

# Executive summary

## What are the current clinical negligence cover arrangements?

Healthcare professionals are required to hold appropriate clinical negligence indemnity cover to cover the costs of claims and damages awarded to patients arising out of negligence. Clinical negligence indemnity cover pays for the compensation costs and legal fees that arise as a result of incidents of clinical negligence. The cover can be an insurance policy, an indemnity arrangement, or a combination of both.

NHS hospital staff meet the requirement to hold appropriate cover through a state-backed scheme called the Clinical Negligence Scheme for Trusts (CNST).

General practitioners (GPs) currently purchase their own indemnity. However, prices have been rising and this has a significant impact on GPs. The Government has announced that it intends to develop a state-backed scheme for GPs and GP staff in England to provide cover for clinical negligence claims arising from GP-delivered NHS services.

However, there remain some healthcare professionals, such as private practitioners and dental professionals, who fall outside of any existing or proposed state-backed scheme. This includes some healthcare professionals in Scotland, Wales and Northern Ireland, for whom professional regulation for healthcare professionals remains a reserved matter for the UK Parliament. These professionals currently make their own insurance or indemnity arrangements. This consultation is about the indemnity cover for these healthcare professionals.

## What are the concerns with current indemnity cover?

There is concern about the stability of the current forms of indemnity cover. This is because:

- the indemnity providers who provide cover for many healthcare professionals do so under discretionary indemnity arrangements meaning that, unlike commercial insurance companies, they have no contractual obligation to meet the cost of any claim against the professionals they cover;
- such indemnity providers have no legal obligation to ensure they have the reserves to cover the cost of claims, raising the risk of a patient, ultimately, being unable to access appropriate compensation;

- they do not have to disclose their full financial position, meaning that healthcare professionals may be unaware of the extent of their financial cover; and
- they are not subject to regulation on financial conduct and fair treatment, leaving healthcare professionals at risk of unfair treatment.

In light of these concerns and rising clinical negligence costs, the Government is launching a public consultation on current clinical negligence cover arrangements, and is seeking the public's views on how to achieve the following objectives of ensuring that:

- patients harmed by the negligence of regulated healthcare professionals can access appropriate compensation;
- regulated healthcare professionals hold stable and sufficiently funded clinical negligence cover, thereby reducing potential risks of prohibitive costs to the healthcare workforce and the patients they treat failing to access appropriate compensation;
- regulated healthcare professionals have greater clarity and confidence about the security and terms of their cover, as well as suitable patient protection in the event of a dispute with their indemnity provider; and
- patients have greater clarity and confidence of their recourse to any compensation.

## **What are the consultation options?**

The consultation seeks views on two options:

- Option 1: leave arrangements as they are; or
- Option 2: change legislation to ensure that all regulated healthcare professionals in the UK not covered by a state-backed indemnity scheme hold appropriate clinical negligence cover that is subject to appropriate supervision, in the case of UK insurers, by the Financial Conduct Authority (FCA) and Prudential Regulation Authority (PRA).

Regulated cover could be achieved by amendments to professional regulation legislation requiring healthcare professionals to purchase regulated insurance only; bringing discretionary products within scope of financial regulation; or a combination of both.

The Government's preferred option (subject to the outcome of the consultation) is option 2. This would ensure that all healthcare professionals with such cover would be protected against unexpected risks.

## **The potential impacts of the two options are as follows:**

Option 1 - Leave arrangements as they are - maintaining existing legislation on clinical negligence cover

The benefit of continuing the provision of unregulated discretionary products is that discretionary providers could continue to have considerable flexibility in how they support their members, in terms of prices and nature of cover. As they do not have to hold set levels of reserves, they may be able to provide lower cost cover than insurance companies. The Government is only aware of a limited number of cases where MDOs have exercised their discretion not to support a member. However, the increase in clinical negligence costs may pose a risk that a provider who provides discretionary indemnity cover may use its discretion not to support a healthcare professional. This could result in a healthcare professional being personally liable, and insufficient, or no, compensation for the patient.

A further risk is the absence of prudential regulation requirements, meaning providers do not have to ensure they have sufficient reserves to meet the costs of claims; that providers are not subject to oversight from established financial regulators; and professionals face a lack of clarity regarding fairness and transparency obligations.

Option 2 - Legislative change

The benefits of this proposal include:

- the lowered risk to patients and healthcare professionals due to cover being contractually enforceable and financially sufficient;
- financial conduct requirements ensuring fair treatment and transparency; and
- the chance for increased competition and innovation in the clinical negligence cover on offer.

However, there are potential difficulties arising from a move to a regulated product. In the transition, current providers may be unable to, or choose not to, continue to provide cover and there could be higher overall costs of clinical negligence cover. Moreover, regulated healthcare professionals would need to ensure that their contract of insurance meets the scope and risk of their practice, and does not exclude relevant activities or have inadequate limits.

Subject to the outcome of this consultation, if the government is minded to introduce regulation, the public would be consulted again on the detail and mechanism of such regulation.

## **Which healthcare professionals are likely to be affected?**

The proposed changes would not affect NHS staff working in hospitals who are covered by CNST. The changes would also not affect GPs and GP staff in relation to their NHS services in England and Wales, as cover for this will be provided under the respective proposed state-backed schemes. The groups that are likely to be most affected by any changes to the current indemnity arrangements are:

- regulated professionals in the NHS who hold indemnity cover which is not currently regulated, such as primary care dentistry;
- private practice of medical doctors and other regulated healthcare professionals, including dentists, who hold indemnity cover that is not currently regulated; and
- healthcare professionals in Northern Ireland and Scotland who are not covered by any state-backed indemnity scheme and for which professional regulation for healthcare professionals remains a reserved matter for the UK Parliament. This could include GPs for their NHS activities if they are not covered by a state-backed scheme and if they hold unregulated cover. There are also healthcare professionals working in Crown Dependencies who are regulated by UK regulators and who may be impacted.

# 1. Introduction

- 1.1 Every healthcare professional, whether they work in the NHS or the private sector, owes a duty of care to act in the best interest of their patients. Healthcare providers must get the basic qualities of care – safety, effectiveness, and patient experience – right every time. There are some unfortunate circumstances, however, where patients and families are harmed, directly or indirectly, by the negligence of their healthcare professional. Future reference to 'regulated healthcare professionals' is in the context of this requirement for them to hold appropriate indemnity arrangements as a condition of registration/grant of licence, if they wish to practise in the UK.
- 1.2 All healthcare professionals who wish to practise in the UK are legally required as a condition of registration with the professional regulator (or in the case of doctors, as a condition of the grant of a licence to practise), to hold appropriate clinical negligence cover for the risks of their practice, covering the costs of defending clinical negligence claims and damages awarded to patients. Professional regulation exists to protect the public from harm and operates on a UK-wide basis. Historically, except in relation to NHS trusts, NHS foundation trusts, and other members of the Clinical Negligence Scheme for Trusts (CNST), clinical negligence cover has been provided by both medical defence organisations (MDOs) which are not subject to prudential and financial conduct regulation in respect of the discretionary clinical negligence indemnity they provide, and insurance companies, which are subject to such regulation.
- 1.3 In October 2017, the former Secretary of State for Health announced plans to introduce a state-backed indemnity scheme for general practice in England in April 2019, noting that the rising cost of clinical negligence is a great source of concern for GPs and impacts negatively on the GP workforce. In May 2018, the Welsh Government also announced their intention to introduce a state scheme for general practice in Wales in April 2019. The Department of Health and Social Care understands that the cost of clinical negligence cover is generally lower in Scotland and the Scottish Government is considering its position on the future of general practice indemnity. In Northern Ireland, the Department of Health (NI) is considering general practice indemnity in order to identify appropriate action and support the continued sustainability of GP services.
- 1.4 Whilst the Department for Health and Social Care is introducing a scheme solely for general practice in England, there are concerns about the security of clinical negligence cover held by regulated healthcare professionals practising in the UK who will not be covered by any state-backed scheme. This includes dental professionals and doctors in private practice.
- 1.5 This consultation considers the future of clinical negligence cover for regulated healthcare professionals practising in the UK. The Government wants to ensure that:

- patients harmed by the negligence of regulated healthcare professionals can access appropriate compensation;
- regulated healthcare professionals hold stable and sufficiently funded clinical negligence cover, thereby reducing potential risks to the healthcare workforce and the patients they treat;
- regulated healthcare professionals have greater clarity and confidence about the security and terms of their cover, as well as suitable consumer protection in the event of a dispute with their provider; and
- and patients have greater clarity and confidence of their recourse to any compensation.

1.6 In practice, the options presented in this document are more likely to affect regulated healthcare professionals practising across the UK, if they have a discretionary clinical negligence indemnity arrangement for activities that are expected to be outside the scope of existing and proposed state-backed indemnity schemes:

- NHS primary care dentistry and private dentistry;
- private practice of medical doctors and other regulated healthcare professionals; and
- healthcare activity within the devolved administrations which is not covered by a state-backed indemnity scheme (for example, if state-backed indemnity schemes for general practice had not been introduced in the devolved administrations by the time regulation, if introduced, came into force). Healthcare professionals working in Crown Dependencies who are regulated by UK regulators may also be impacted.

The options may also affect providers based in the UK who provide discretionary clinical negligence indemnity to healthcare professionals practising in overseas jurisdictions. This could be if UK indemnity providers that are not providing insurance are brought within the scope of the regulatory perimeter of the Regulated Activities Order 2001 – RAO. More information is set out at paragraph 5.19.

The current indemnity arrangements and options set out in this document apply across the UK. The regulation of financial services under the Financial Services and Markets Act 2000 (FSMA) is of UK extent. The devolved position for professional regulation is set out below:

- in Wales, professional regulation is a matter reserved to the UK Parliament;
- in Scotland, only the professions that have been created since the devolution settlement are a devolved matter. This means that the General Dental Council, the General Pharmaceutical Council, and the Health and Care Professions Council are accountable



## Appropriate clinical negligence cover

to the Scottish Parliament as well as to the UK Parliament in respect of certain professional groups that have become regulated since the Scotland Act 1998 (for example, dental technicians and dental nurses); and

- in Northern Ireland, health regulation is a transferred matter, but the only piece of legislation specific to Northern Ireland is the Pharmacy (Northern Ireland) Order 1976.

- 1.7 If, following the outcome of this consultation, Government is minded to introduce regulation, this would require further consultation on the shape of any professional and financial regulation and specific changes to legislation. The process of consultation and laying of regulations could take a further 18 to 24 months, and the actual 'start date' for any regulation would be dependent on a decision about appropriate transition periods.
- 1.8 A list of key terms used within this document is set out in the **Glossary**.

## 2. Policy background

### Introduction

- 2.1 Clinical negligence arises where there is a breach of the common law duty of care owed to a patient by members of the healthcare professions or by others acting on their decisions or judgements, or omitting to act, which causes harm or physical injury to a patient. If a patient has suffered harm or injury as a result of clinical negligence, the patient or their representative may make a claim for damages against the clinicians or their employers.
- 2.2 The claim process for clinical negligence can be long, with many years between when the incident of alleged negligence occurs, when a potential claim materialises, and when any settlement is paid out to the affected party. The limitation period for an adult to bring a claim is usually three years from the date of the incident or the claimant's knowledge of having suffered loss or injury (for example, in the event of a delayed diagnosis), whichever is later. For children, the three-year limitation period begins when the child reaches the age of maturity, generally the age of 18 (if someone has not brought a claim on their behalf before). The limitation period can be extended at the court's discretion. The delay between the incident, claim, and settlement can create uncertainty for indemnity providers in projecting the cost of future settlements, and in reserving adequate financial resources accordingly.

### Clinical negligence in Trusts and other NHS bodies

- 2.3 NHS bodies and organisations are responsible for any clinical negligence of their employees. Since 1996, the NHS Litigation Authority, (known as NHS Resolution since 2017) has, on behalf of the Secretary of State, administered an indemnity scheme covering clinical negligence claims arising from liabilities incurred in the provisions of NHS secondary care. This scheme is referred to as the Clinical Negligence Scheme for Trusts (CNST) and now covers the clinical negligence liabilities of NHS Trusts and other bodies, such as clinical commissioning groups (CCGs) and NHS England, for incidents that occurred after they became members of the scheme. There is one very limited exception where an agreement is reached for CNST to cover a particular liability that arose prior to joining CNST. There are similar arrangements in relation to secondary care in the devolved administrations, with the Welsh Risk Pool in Wales, Clinical Negligence and Other Risk Indemnity Schemes (CNORIS) in Scotland, and HSC Trusts and the Department of Health (Northern Ireland) in Northern Ireland.

## The rising cost of clinical negligence

- 2.4 In recent years, the cost of clinical negligence for Trusts has risen and is projected to continue to rise significantly. The cash spending on CNST has quadrupled from £0.4bn in 2006-07 to £1.6bn in 2016-17. Multi-million-pound damages awards are not uncommon, particularly for clinical negligence in areas such as birth injury and surgery. Between 2006-07 and 2016-17, clinical negligence pay-outs for damages awarded for high-value birth injury claims for patients with cerebral palsy increased 9% year on year. The Government understands that the costs of claims relating to incidents of clinical negligence in other healthcare settings have also been rising.
- 2.5 The Government is concerned about the rising cost of clinical negligence cases and is developing a cross-government strategy to control costs, as challenged by the National Audit Office (NAO)<sup>i</sup> and Public Accounts Committee (PAC)<sup>ii</sup>. The Department of Health and Social Care is working with the Ministry of Justice, NHS Resolution, and others as appropriate to develop this strategy.

## GP Indemnity

- 2.6 Following concerns relating to the impact of rising indemnity costs on the GP workforce, the former Secretary of State announced in October 2017 that the Department of Health and Social Care is planning the development of a state-backed indemnity scheme for general practice in England, to be introduced in April 2019. In May 2018, the Welsh Government also announced their intention to introduce a state scheme for general practice in Wales in April 2019.
- 2.7 It is planned that the scheme in England will cover liabilities for clinical negligence arising from the activities of all contractors (and their employees) when providing primary medical services. Specifically, this refers to contractual arrangements made under Part 4 of the NHS Act 2006: General Medical Services (GMS), Personal Medical Services (PMS), and Alternative Provider Medical Services (APMS) contracts, plus any other integrated urgent care delivered through schedule 2L (Provisions Applicable to Primary Care Services) of the NHS standard contract. Government is working with stakeholders to develop the scope of the state-backed scheme, to ensure that it supports the development of new models of care and meets the needs of current and future general practice staff.
- 2.8 It is the current intention that the following activities will not be included in the state backed scheme: NHS primary care dentistry and private dentistry, private healthcare, including that provided by general practice staff, and community pharmacy and optometry.

## Incidents of clinical negligence not covered by state-backed indemnity

- 2.9 Currently, regulated healthcare professionals who do not work for organisations covered by state-backed indemnity schemes such as CNST, including those working in general practice, primary care dentistry, or in private or voluntary settings, are covered for clinical negligence through either discretionary clinical negligence indemnity provided as a benefit of membership of MDOs, or contracts of insurance with commercial insurers.
- 2.10 The recent case of malpractice in a clinical setting, of convicted breast surgeon Ian Paterson, has raised concerns about indemnity arrangements within private healthcare.
- 2.11 In March 2018, the Independent Inquiry into the Paterson case announced its terms of reference, including consideration of issues relating to<sup>iii</sup>:
- the role of independent sector insurers, medical indemnifiers and MDOs (including sharing of data); and
  - the arrangements for medical indemnity cover for healthcare professionals in relation to all patients receiving care in the independent sector, whether such patients are medically insured or their treatment is NHS-funded or self-funded.

As the Department of Health and Social Care develops policy on clinical negligence indemnity it will consider the findings of the Inquiry.

## Healthcare professional indemnity requirements

- 2.12 From 2004, the Government began to consider whether it should be compulsory for regulated healthcare professionals to hold clinical negligence cover (including insurance and and/or discretionary clinical negligence indemnity), following several cases where a claim was made against a healthcare professional who was operating without discretionary clinical negligence indemnity or insurance, leaving the patient without recourse.
- 2.13 In 2011, the Government accepted the recommendations of the independent Finlay Scott review which recommended that making insurance or any other indemnity arrangement (i.e. discretionary indemnity) a condition of registration (or a grant of licence) for healthcare professionals was the most cost-effective and proportionate means of achieving the Government's stated policy objective that all healthcare professionals must have clinical negligence cover<sup>iv</sup>. Following this review, European Union Directive 2011/24/EU on the application of patients' rights in cross-border healthcare also placed a requirement on Member States to ensure that they have systems of professional liability insurance or similar arrangements in place in relation to provision of cross-border healthcare.

- 2.14 Through the Health Care and Associated Professions (Indemnity Arrangements) Order 2014 (S I 2014/1887), the Government amended existing professional standards legislation, introducing the requirement for all registered healthcare professionals to hold appropriate indemnity arrangements in respect of their practice. The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 introduced a legislative requirement for pharmacists in Northern Ireland.
- 2.15 **It is the legal requirement of registration (and for doctors, a condition of the grant of licence to practise) that all regulated healthcare professionals practising in the UK, hold appropriate indemnity arrangements in respect of their practice. This may include a policy of insurance, any other arrangements made for the purposes of indemnifying a person (i.e. discretionary clinical negligence indemnity), or a combination of the two.** It is for the healthcare professional regulatory bodies to decide when and what information must be provided by registrants to show that such a policy or arrangement is in place.
- 2.16 The precise terms, scope, and extent of the cover which must be obtained is a matter for the regulated healthcare professional and may vary depending on the regulator concerned. For example, the General Osteopathic Council requires that all osteopaths practicing in the UK acquire professional indemnity insurance with a minimum cover of £5 million. However, regulated healthcare professionals must ensure that their cover is adequate and appropriate, providing cover against liabilities that may be incurred in practising, in respect of their nature and extent of the risks of their practice. Annex A sets out the healthcare professional regulatory bodies' current definitions of adequate cover.
- 2.17 The rising cost of clinical negligence cover generally have renewed concerns about the future of clinical negligence cover for regulated healthcare professionals more widely. Chapter 4 of this document (Policy objectives and concerns) explores the differences between discretionary and contractual cover, and the absence of regulatory requirements for the provision of discretionary indemnity, in terms of holding adequate financial resources to meet the cost of future claims, disclosure of the provider's financial position to the PRA, and financial conduct more generally.
- 2.18 A recent example in which a professional healthcare regulator ruled on the appropriateness of healthcare professionals' clinical negligence cover was Nursing and Midwifery Council's (NMC) judgement in respect of an indemnity scheme for independent midwives (IMUK/Lucina), under which there was no contractual obligation to meet a claim and where benefits were limited to the total funds available in the scheme. The NMC's judgement, which was upheld by the High Court, was that the cover did not provide sufficient financial protection to IMUK/Lucina's members, and as such, was not 'appropriate cover' for the purposes of the professional regulation requirements. This was due to the risk of substantial damages being awarded in the event of catastrophic injury, which the scheme would not be financially capable of meeting<sup>v</sup>.

# 3. Clinical negligence cover

## Current situation

- 3.1 Under current healthcare professional standards legislation, regulated healthcare professionals practising in the UK who are not covered by any state-backed indemnity schemes (such as CNST and the Welsh Risk Pool) may hold clinical negligence cover through a contract of insurance from an insurance company, or discretionary indemnity as a benefit of membership of an MDO or another provider. While these two forms of cover may appear to be similar in substance, there are key differences in the cover provided:
- 3.2 Table 1: Different forms of clinical negligence cover available (outside of state-backed indemnity). The regulatory requirements in this table relate solely to the provision of clinical negligence cover and not to other activities or services the organisation may provide (for example, advice and support).

	Discretionary clinical negligence indemnity	Contract of insurance
Relationship with healthcare professional	Typically offered to healthcare professionals directly as a benefit of membership of an MDO, with healthcare professionals paying an annual membership subscription.	Typically offered to healthcare professionals via an insurance broker on behalf of a commercial insurer, or less frequently, direct from an insurer. Healthcare professionals pay an annual insurance premium.
Limits on cover	No explicit limit on the cover offered (subject to funds available to the indemnity provider). The indemnity provider will exercise its discretion whether (and to what extent) to assist the healthcare professional. The Government is only aware of a limited number of cases where an MDO has exercised its discretion not to support a member.	The terms of the insurance policy will specify with certainty the nature of the cover that will be provided to the healthcare professional and in what circumstances. Cover is generally subject to caps, and frequently excesses and deductibles, on the value of claims that the healthcare professional is covered for (e.g. up to £10m), and may exclude particular clinical activities.
Period of cover	Typically offered on a 'claims-occurring' basis, but there are recent examples of providers of discretionary indemnity offering cover on a 'claims-made' or 'claims-paid' basis.	Typically offered on a 'claims-made' basis requiring run-off cover, but there are recent examples of the commercial insurance market offering 'claims-occurring' cover.

Appropriate clinical negligence cover

<p>Financial solvency requirements</p>	<p>No regulatory requirement for an indemnity provider to hold adequate reserves to meet expected future claims, and capital to absorb unexpected risks.</p>	<p>An EU authorised insurance provider (including a UK insurer) must comply with prudential regulatory requirements. Where it satisfies certain minimum thresholds, this will be the Solvency II prudential regime that requires (among other things), that the insurer holds adequate reserves to meet insurance claims when they fall due, and to hold capital to absorb unexpected risks so that it can continue to meet liabilities as they fall due.</p> <p>The PRA is the supervisory authority in the UK responsible for ensuring compliance with Solvency II. The FCA prudentially regulates insurance intermediaries, for example, around protecting client money.</p>
<p>Financial conduct requirements</p>	<p>While the organisation and its directors may have legal duties to its members to comply with its constitution, there is no regulatory requirement for a provider of discretionary indemnity to adhere to financial conduct regulation around treating customers (in this case, its members) fairly in respect of the discretionary indemnity provided.</p>	<p>A UK insurer is required to comply with financial conduct regulation around the FCA's Principles for Businesses, including a requirement to treat its customers fairly<sup>vi</sup>. This may also be the case for insurers that are authorised in other EU member states or in third country jurisdictions. The FCA is the financial conduct regulator for UK insurers.</p>
<p>Regulatory oversight and transparency</p>	<p>The provision of discretionary indemnity is not subject to any regulatory oversight from the established financial regulators – in the UK these are the FCA and the PRA.</p>	<p>Insurers are required to disclose their full financial position and are subject to reporting and oversight by regulators - in the UK these are the FCA and the PRA. Insurers are required to deal in an open and co-operative manner with their regulators, disclosing all relevant information of which a regulator would reasonably expect notice.</p>

Access to adequate redress	A healthcare professional would not be eligible for the Financial Services Compensation Scheme in the event that their indemnity provider declined to exercise its discretion to assist them or was otherwise unable to cover claims. Healthcare professionals are additionally unable to access the Financial Ombudsman Service in the event of a dispute with their indemnity provider.	Insurance policyholders are eligible for compensation from the Financial Services Compensation Scheme (funded by a levy on insurers) if an insurer is unable, or likely to be unable, to pay claims against it. This provides policyholders with financial protection in the event of a failure with their insurer. Insurance policyholders additionally have access to the Financial Ombudsman Service in the event of a dispute with an authorised insurance firm that is still trading.
----------------------------	---	--

- 3.3 Government understands that GPs and general practice staff hold the benefit of discretionary indemnity through membership of an MDO. Some GPs may also hold an insurance policy. From April 2019, the Government plans to introduce a state-backed indemnity scheme for general practice in England. The Welsh Government also intends to introduce a state backed indemnity scheme to cover general practice in Wales from April 2019.
- 3.4 Other healthcare professionals, including dentists and dental professionals and doctors for their fee-paying work, community pharmacist, optometrists and chiropractors, may also hold cover from a discretionary indemnity provider or an insurance provider.
- 3.5 Discretionary clinical negligence indemnity for healthcare professionals has existed in the UK since the 1880s. There are four MDOs providing discretionary clinical negligence indemnity to healthcare professionals in the UK: the Medical Defence Union (MDU), the Medical Protection Society (MPS), the Medical and Dental Defence Union of Scotland (MDDUS), and since July 2017, the Medical Defense Society (MDS). These are mutual, not-for-profit organisations that are owned by their members. Alongside clinical negligence indemnity, MDOs also provide assistance for professional matters (for example, GMC hearings, and coroners' inquests) and medico-legal support. The Royal College of Nursing indemnity scheme also provides discretionary indemnity to nursing professionals who are self-employed, do not work under a contract of employment (such as agency or bank workers), volunteers, and those acting in a Good Samaritan capacity. There is also an active commercial insurance market in the provision of clinical negligence and professional cover in the UK.
- 3.6 Clinical negligence can arise in the conduct of clinical research. The UK Policy Framework for Health and Social Care Research includes the principle that "Adequate



## Appropriate clinical negligence cover

indemnity provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.”<sup>vii</sup>

- 3.7 CNST (or equivalent schemes in the devolved administrations) may cover claims arising from clinical negligence arising from research taking place under an NHS duty of care in an NHS Trust or Board. Outside of the scope of CNST (or its equivalent schemes), cover for harm arising from clinical negligence in the conduct of research is normally provided by membership of an MDO (e.g. research taking place under an NHS duty of care in an independent contractor GP Practice), other form of mutual discretionary provision, or by a commercial insurance policy (e.g. research under the duty of care of a university or pharmaceutical company in academic or commercial facility). Indemnity for harm arising from the design or management of research projects falls outside of the scope of this consultation.
- 3.8 In many sectors where a relationship of indemnity (compensation for any loss or liability which one person has incurred) exists, such as car insurance, house insurance, and professional indemnity insurance, it is provided as a contract of insurance by an insurance company and is regulated by the PRA and FCA, in the case of UK insurers. According to the PRA's approach to insurance supervision, it is likely that, in the absence of prudential regulation, insurers would be less 'safe and sound' and 'deliver a lower standard of policyholder protection than would be in the public interest'.<sup>viii</sup>

# 4. Policy objectives and concerns

## Policy objectives

- 4.1 The Government is considering the future of clinical negligence cover for regulated healthcare professionals and asking for the public's views on how to achieve the following objectives. The Government wants to ensure that:
- patients harmed by the negligence of regulated healthcare professionals can access appropriate compensation;
  - regulated healthcare professionals hold stable and sufficiently funded clinical negligence cover, thereby reducing potential risks to the healthcare workforce and the patients they treat;
  - regulated healthcare professionals have greater clarity and confidence about the security and terms of their cover, as well as suitable consumer protection in the event of a dispute with their provider, and
  - patients have greater clarity and confidence of their recourse to any compensation.
- 4.2 In seeking to achieve these objectives, the Government will consider any impacts on patients, healthcare professionals, and the organisations for which they work. The Government will also consider any adverse impacts that the proposed changes may have on the availability and affordability of clinical negligence cover in the market.

# Policy concerns

- 4.3 Given the current situation of indemnity arrangements and the Government's policy objectives in this area, the Government has identified the following policy concerns:

## i) Discretionary and contractual cover

- 4.4 If a healthcare professional has the benefit of a discretionary clinical negligence indemnity arrangement, assistance to meet a clinical negligence claim is provided at the discretion of the provider and the provider has no contractual obligation to meet the costs of the claim. The potential benefit of this form of cover is that it may allow the indemnity provider to exercise its discretion in circumstances where the professional would not otherwise ordinarily have been covered had they held a contract of insurance due to caps and exclusions (this will depend on the scope of cover offered by commercial insurers).
- 4.5 The Government is only aware of a limited number of cases where MDOs have exercised their discretion not to support a member. For example, in the Paterson case an MDO chose not to support a member who acted criminally. However, insurance cover would normally have exclusions that prevent pay-outs for deliberate malpractice. In 2012, the Government of the Republic of Ireland concluded a €45 million settlement agreement with the Medical Defence Union (MDU), following a decision by the MDU not to exercise its discretion to provide assistance and indemnity to large numbers of consultant obstetricians in respect of historical liabilities for clinical negligence claims<sup>ix</sup>.
- 4.6 While the flexibility of discretionary indemnity may be beneficial in some circumstances, a risk remains that a member could be refused assistance if their provider chooses not to support the member in defending a claim against them, or to pay all or a proportion of an award of compensation (and any legal costs) made by a court agreed by way of settlement. This could be for any reason including financial difficulty of the provider. Where the provider does not meet the claim in full, the healthcare professional would be left without the backing of the provider and therefore be personally exposed for any compensation or costs which are payable. A healthcare provider may also be exposed for any compensation or costs if they are vicariously liable for the incident of clinical negligence, potentially reducing their financial resources for delivering care.
- 4.7 Discretionary indemnity arguably offers less certainty to regulated healthcare professionals than a contract of insurance. A contract of insurance is a contingent liability: there is a legal obligation to pay out if an incident is within the terms of the policy which will be clear to the policyholder – in this case the professional - at the point of purchase (and which may influence their decision to purchase). Although there may be some disagreement as to whether the incident of negligence is covered by a policy of insurance as a matter of law, the insurer does not have discretion as to whether to

pay out. At the heart of a contract of insurance is a legally enforceable obligation to provide some form of benefit (usually in the form of a monetary payment) upon the occurrence of a certain event, which may be subject to specified caps and exclusions. In contrast, MDOs offering discretionary indemnity do so on the basis that their discretion is absolute, that any assistance offered is at their sole discretion and they therefore are not obliged to pay out in any circumstances<sup>x</sup>. Consequently, regulated healthcare professionals have less visibility, certainty, and assurance as to what incidents may or may not be covered under discretionary indemnity. However, we should not assume that healthcare professionals purchasing insurance cover have a greater understanding of the product than those covered by discretionary indemnity arrangements.

- 4.8 A related and crucial risk of discretionary indemnity is that the existence of discretion could leave the patient who has made the claim against the healthcare professional without recourse to an adequate remedy (i.e. compensation) for the harm or injury sustained. If a healthcare professional without cover from their indemnity provider does not have the means to pay any compensation or costs, then the patient may have no means by which to obtain compensation. It is the right of all NHS patients, as stated in the NHS Constitution for England, to receive compensation where they have been harmed by negligent treatment<sup>xi</sup>.
- 4.9 With contractual cover, regulated healthcare professionals need to ensure that the scope and risk of their practice are reflected in the terms and conditions of their contract of insurance – that it does not exclude any relevant activities and that the limit of cover is appropriate.
- 4.10 With either discretionary indemnity or a contract of insurance, if this is provided on a claims-made or claims-paid basis, the regulated healthcare professional will need to purchase run-off cover to be protected for any claims arising after the period of their membership or after their policy expires for unreported incidents that occurred before their membership or policy ended. If there is not appropriate enforcement and education in place to ensure that healthcare professionals purchase run-off cover, then there is also the risk that patients may not be appropriately compensated for any future claim made in respect of such historical acts.

## **ii) Financially sufficient cover**

- 4.11 While a regulated healthcare professional must hold cover that is judged to be ‘appropriate cover’ under current legal requirements, there is no legal obligation for an indemnity provider offering discretionary clinical negligence indemnity to ensure that it is backed by adequate financial resources to pay the indemnity (damages) in practice.
- 4.12 In order to provide full financial protection to members or policyholders (and ultimately to pay out to the relevant party – in the case of clinical negligence - patients), indemnity

## Appropriate clinical negligence cover

providers should ensure that they have the financial resources to meet the cost of future claims (i.e. have sufficient assets to meet their liabilities).

- 4.13 There are, however, different requirements on the provision of discretionary and contractual clinical negligence cover to ensure that the provider holds sufficient financial resources in place to meet the cost of these claims. An insurance company authorised in the UK or in another EU member state offering a contract of insurance will need to comply with Solvency II prudential regulation (assuming certain minimum thresholds are satisfied) including the requirement to hold adequate reserves to meet insurance claims as they arise and to hold sufficient capital to enable them to absorb unexpected losses and to continue to be able to meet liabilities as they fall due<sup>xii</sup>. These regulatory requirements do not apply to the provision of discretionary clinical negligence indemnity.
- 4.14 The absence of regulatory requirements for providers of discretionary indemnity to hold adequate reserves and capital, and the fact that such discretionary indemnity is not subject to Insurance Premium Tax or Financial Services Compensation Scheme levies, may enable these providers to offer more affordable clinical negligence cover to healthcare professionals than insurance companies. However, this may expose the indemnity provider, and healthcare professionals and patients by association, to greater financial risk if it transpires that the provider does not have the financial resources to satisfy claims.
- 4.15 If a healthcare professional obtains discretionary indemnity, and therefore the provision of this cover is not subject to prudential requirements, there is a risk that their provider may not be able to meet all future claim payments (if such claim payments exceed the available assets of the provider). In such a scenario, the provider would need to decide whether to restrict the amount eventually settled to its professional members, perhaps increasing the aforementioned risk of healthcare professionals being personally exposed to legal costs and damages, and patients left without recourse or compensation.
- 4.16 Furthermore, if the provider of discretionary indemnity is also a mutual organisation and requires further financial resources, it may undertake a cash call on its membership for extra funds, if empowered to do so by its Articles of Association.
- 4.17 The risk that a provider of discretionary indemnity may not be able to meet the cost of future claims may be increased by the following factors in the market for clinical negligence cover:
- i) There is generally a long delay between the incident of clinical negligence, a claim being reported, and settlement of the claim. This places pressure on indemnity providers to ensure that their revenue from pricing, i.e. their membership subscriptions or premia, can meet the projected cost of claims in the future, and is subject to considerable uncertainty.

ii) If providers competed on price to attract members or policyholders, this could place them in a difficult position of needing to realise two competing imperatives: the need to adequately reserve to meet the cost of future claims over the long-term, and the pressure to compete on price in the short-term. Incumbents could also be under threat of new entrants entering the market without a long tail of liabilities, which are able to attract members or policyholders on the basis of price.

iii) Without any regulatory requirements to adequately reserve and hold sufficient capital, providers of discretionary indemnity, and by association healthcare professionals and patients, may be more vulnerable to external developments, such as a change in wider economic conditions, legal precedent, or the volume of claims. The organisations involved in managing clinical negligence claims report that the change in the Personal Injury Discount Rate (PIDR) in February 2017 increased the cost of long-term clinical negligence liabilities<sup>xiii</sup>. The Government's Civil Liability Bill includes a new mechanism to set the PIDR <sup>xiv</sup>.

- 4.18 In relation to discretionary clinical negligence indemnity where no prudential regulation currently exists, the healthcare professional would be unable to seek compensation from the Financial Services Compensation Scheme in the event of a provider's inability to pay out under the indemnity, and would not be able to seek assistance from the Financial Ombudsman where they had a complaint. The healthcare professional would therefore remain personally financially exposed to the extent that their indemnity provider refused to cover the cost of the claim, limiting the recourse and compensation available to their patient.
- 4.19 If an indemnity provider is not subject to prudential regulation, this may limit the forms of compensation available to patients from a court settlement. Settlement of clinical negligence claims can be way of a lump sum payment, or a Periodic Payment Order (PPO). PPOs are court orders that provide annual compensation payments to the claimant that can cover their care costs, case management costs, and any future expenses. These may be awarded, for example, if there is significant uncertainty over how many years the claimant may live and require care, or to protect the claimant from poor investment decisions on the lump sum compensation.
- 4.20 Under the Damages Act 1996, in order to award a PPO the court will need to be satisfied that the continuity of payment under the order is reasonably secure. The Act specifically provides that continuity of payment will be considered reasonably secure where the PPO is backed by a government guarantee or payment, or protected under a financial compensation scheme established under the Financial Services and Markets Act 2000. In other cases, the court must be satisfied on the facts that the proposed method of funding the payment is reasonably secure (i.e. that the method of funding can be maintained for the required duration and will meet the level of payment ordered by the court). Non-governmental indemnifiers have to set aside adequate reserves to meet these obligations with the result that unregulated indemnifiers are generally unable to provide PPOs.

4.21 In the context of the rising costs of clinical negligence, Government wants to ensure that regulated healthcare professionals can continue to access stable cover that is appropriate for the risks of their practice. If there is unaffordable or insufficient clinical negligence cover available in the market as a result of indemnity providers becoming unable to meet the cost of claims, then this may affect the ability of healthcare professionals to practise, potentially placing a financial burden on the healthcare workforce, and disrupting the delivery of healthcare services.

### iii) Regulatory oversight and transparency

4.22 The risk that providers of discretionary indemnity may face a situation in which they do not hold sufficient financial resources to support healthcare professionals may be increased by an absence of appropriate regulatory oversight and transparency. Providers of discretionary indemnity (principally the MDOs) are not required to disclose their full financial position in their Audited Accounts in respect of such cover and are not subject to the same standards of reporting, disclosure, and oversight by regulators (the FCA and PRA) as insurance companies.

4.23 Regulated healthcare professionals may therefore have less assurance about the extent of their financial protection or, conversely, exposure, and patients and the public may have less certainty and confidence in the extent to which recourse is available.

### iv) Financial conduct and fair treatment

4.24 The absence of regulatory oversight from the FCA into the provision of discretionary indemnity may also have consequences for healthcare professionals in terms of financial conduct and fair treatment. In the context of the insurance industry, it is a key principle of financial conduct regulation that policyholders are provided with information on the scope and circumstances under which they may be covered under an insurance contract, and are treated fairly.

4.25 Regulated insurance companies must comply with the FCA's Principles for Businesses. These include, but are not limited to:

- **Integrity:** A firm must conduct its business with integrity;
- **Financial prudence:** A firm must maintain adequate financial resources;
- **Market conduct:** A firm must observe proper standards of market conduct;
- **Customers' interests:** A firm must pay due regard to the interest of its customers and treat them fairly. FCA guidance on treating customers fairly sets out 6 outcomes,

including that consumers are provided with clear information and are kept appropriately informed before, during, and after the point of sale, and that consumers are provided with products that firms have led them to expect<sup>xv</sup>;

- **Communications with clients:** A firm must pay due regard to the information needs of its clients and communicate information to them in a way which is clear, fair, and is not misleading;
- **Relations with regulators:** A firm must deal with its regulators in an open and cooperative way, and must disclose to the FCA appropriately anything relating to the firm of which that regulator would reasonably expect notice.

4.26 Although the predominant providers of discretionary indemnity, the MDOs are mutual organisations with Articles of Association that set out their responsibilities in respect of their members, they are not subject to clearly defined regulatory duties to treat their members fairly. There is no regulatory framework for members to raise a complaint, should they consider their treatment by an MDO to be unfair. A member of such a mutual organisation would therefore have no recourse but to take legal action through the courts to receive any relief from unfair treatment, which may be a time consuming and expensive exercise, with no guarantee of success. In contrast, policyholders under a contract of insurance are able to raise complaints with the Financial Ombudsman Service and seek compensation if they suffer from unfair treatment at the hands of their insurance provider, without incurring any cost.

4.27 Alongside potential uncertainty about their exposure to financial risk, it is also unclear the extent to which regulated healthcare professionals are informed and aware of the terms and scope of their cover. A survey commissioned by the Department of Health and Social Care showed that over half of surveyed GPs, or practice managers who responded on their behalf, are unaware of the type of cover they hold (specifically whether this is a claims-made, claims-paid, or claims-occurring product)<sup>xvi</sup>. It is also unclear the extent to which regulated healthcare professionals are aware of the differences between discretionary and contractual (insurance) cover.



## 5. Policy options

5.1 The Government has identified the following options for consideration:

- i) Maintaining the existing legislation and arrangements related to clinical negligence cover;
- ii) Legislative change by way of secondary legislation to ensure that regulated healthcare professionals in the UK (not covered by a state-backed scheme) hold appropriate clinical negligence cover that is subject to appropriate supervision by the FCA and PRA.

5.2 In practice, the options presented in this document are more likely to affect the following activities for which regulated healthcare professionals across the UK currently hold the benefit of discretionary clinical negligence indemnity and which are expected to be outside the scope of existing and proposed state-backed indemnity schemes:

- NHS primary care dentistry and private dentistry;
- Private practice of medical doctors and other regulated healthcare professionals;
- Healthcare activities within the devolved administrations which are not covered by a state-backed indemnity scheme (for example, if state-backed indemnity schemes for general practice had not been introduced in the devolved administrations by the time when regulation, if introduced, came into force).

5.3 The options may also affect providers based in the UK who provide discretionary clinical negligence indemnity to healthcare professionals practising in overseas jurisdictions (if UK indemnity providers that are not providing insurance are brought within the scope of the regulatory perimeter of the Regulated Activities Order 2001 – RAO, please see paragraph 5.18).

5.4 The Government understands that there are a number of other healthcare professionals, of which the majority hold contracts of insurance for their indemnity cover, e.g. optometrists, community pharmacists and chiropractors. The Government therefore does not expect that they would be directly impacted in practice by the options presented in this document.

## **i) Maintaining the existing legislation and arrangements related to clinical negligence cover, 'do nothing'**

- 5.5 This option would involve regulated healthcare professionals practising in the UK not covered by state-backed indemnity schemes continuing to be allowed to hold the benefit of discretionary clinical negligence indemnity as permitted in current professional standards legislation. As discussed in the 'Policy concerns' section of this document, there are a number of potential benefits and risks with the existing arrangements that are summarised below:

### **Potential benefits**

- 5.6 Discretionary indemnity may offer indemnity providers greater flexibility to support their members, as there is no explicit limit on the extent of financial support offered (provided that the indemnity provider has the adequate financial resources), or on the activities that may be supported. While MDOs provide assistance at their discretion and not through a contractual obligation to meet the cost of any claim, the Government is only aware of a limited number of cases where MDOs have exercised their discretion not to support a member.
- 5.7 The absence of regulatory requirements for providers of discretionary indemnity to reserve adequately to meet their liabilities and hold sufficient capital, and the fact that they are not subject to paying Insurance Premium Tax or Financial Services Compensation Scheme levies, may enable these providers to offer more affordable cover to healthcare professionals than insurance companies, particularly as clinical negligence costs are rising. The potential cost benefit for regulated healthcare professionals, however, needs to be considered against the risks of providers of discretionary indemnity declining to exercise their discretion in favour of their members and the potential for patients to subsequently be denied compensation.
- 5.8 MDOs have generally provided cover for their members on a 'claims-occurring' or 'occurrence' basis, meaning that cover is provided for incidents of negligence which occur during the membership period, regardless of when the claim for that negligence is made. A key advantage of this form of cover is that, when the healthcare professional stops practising or changes indemnity provider, they do not need to purchase run-off cover. Under the alternative 'claims-made' and 'claims-paid' forms of cover, cover is provided for any claim that accrues, is made and reported (and in the case of 'claims-paid' only, settled) during the policy or membership period. This means that a professional would need to continue their policy or membership, or purchase run-off cover after they have changed insurance provider, moved indemnity provider, or ceased practising, to remain protected against future claims arising from unreported incidents of negligence that occurred during the previous policy or membership period. This may need to be considered by professional regulators in assessing whether a professional's

cover is adequate. Claims-made coverage has traditionally been favoured by the commercial insurance industry, but there is no restriction on commercial insurers offering claims-occurring cover, and there are examples of some insurers offering claims-occurring policies for clinical negligence cover. Furthermore, more recently MDOs have started to offer discretionary indemnity on a claims-made and claims-paid basis, so the number of regulated healthcare professionals who are required to obtain run-off cover will increase in accordance with movements to such products in any event.

## Potential risks

- 5.9 While the Government is only aware of a limited number of cases where MDOs have exercised their discretion not to support a member, there remains the potential risk to patient recourse and the security of healthcare professionals' cover if the indemnity provider refuses to assist a regulated healthcare professional in defending a claim or paying compensation. In a scenario where a professional is not supported by their indemnity provider and is personally exposed to the cost of court action and damages, the patient could be left with no recourse or compensation for their harm or injury.
- 5.10 The absence of regulatory requirements for the provision of discretionary indemnity in terms of reserving adequately to meet expected claims raises the risk that providers may not be able to meet the cost of claims in the future, for example, because of an external shock or changes in the market. This may increase the risk of an indemnity provider exercising their discretion not to support their members, with patients losing out on potential compensation as a result, or the risk of insufficient and/or unaffordable clinical negligence cover in the market.
- 5.11 Under current arrangements, providers of discretionary clinical negligence indemnity are not subject to FCA or PRA oversight or regulatory reporting requirements in respect of this cover, as regulated insurance companies are for contracts of insurance. This may increase the risk that an indemnity provider cannot meet the cost of expected claims, and healthcare professionals are left without sufficient financial protection. It may not also provide healthcare professionals with reassurance about the extent of their financial protection, or conversely, exposure, and the public and patients with confidence in recourse for clinical negligence.
- 5.12 It is not clear how far regulated healthcare professionals are currently informed and aware of the terms and scope of the cover provided by discretionary indemnity arrangements (e.g. how the discretionary indemnity works, what will be covered, and whether the indemnity operates on a claims-made or claims-occurring basis), in comparison with a contract of insurance that sets out specific terms and conditions under which a policyholder is covered, and is subject to financial conduct regulation. However, we should not assume that healthcare professionals purchasing insurance cover have a better understanding of the product, than those covered by discretionary indemnity arrangements.

## Conclusion

- 5.13 As the Government's key objectives in this area are to ensure that patients can access appropriate compensation and that healthcare professionals are not personally financially exposed to individual claims of clinical negligence, the Government does not believe that doing nothing would be a proportionate response to the risks identified above. **This option is not preferred by the Government at this stage.**
- 5.14 The Government considered whether it may be possible to achieve its objectives through non-legislative changes, e.g. the professional healthcare regulators amending their requirements for adequate and appropriate cover, or through issuing guidance on the benefits and risks of different forms of clinical negligence cover. This is not a preferred approach for Government, however, given the absence of certainty and stability that this may provide to stakeholders in comparison to legislation and the Government's desire to pursue a co-ordinated approach across all regulated healthcare professionals.

### **ii) Legislative change by way of secondary legislation to ensure that regulated healthcare professionals in the UK (not covered by a state-backed scheme) hold appropriate clinical negligence cover that is subject to appropriate supervision by the FCA and PRA.**

- 5.15 This option could be achieved through the following routes:

#### **a) Amendments to healthcare professional standards legislation**

- 5.16 This would require all regulated healthcare professionals in the UK, not otherwise covered by a state-backed indemnity scheme, to hold policies of insurance in order to satisfy the regulatory requirement to have 'appropriate' cover in order to practise.
- 5.17 Regulated healthcare professionals would need to purchase such cover from a regulated insurance provider (not from an organisation offering discretionary clinical negligence indemnity), unless they were covered by a state-backed indemnity scheme. This would require amendments to the relevant primary and secondary professional regulatory legislation<sup>xvii</sup>. The mechanism for these amendments would be secondary legislation through Orders in Privy Council (section 60 of the Health Act 1999).

5.18 Introducing changes via professional standards legislation would mean that discretionary indemnity cover for clinical negligence would no longer operate in the UK as professionals would need to hold a regulated product in order to meet their regulatory requirement to have appropriate cover to practise, or be covered by a state scheme. It would therefore be highly unlikely that any indemnity provider operating from another jurisdiction would seek to provide discretionary indemnity to regulated healthcare professionals in the UK.

## **b) Amendments to financial regulation (the Regulated Activities Order 2001 - "RAO")**

5.19 The financial regulation route would bring the provision of clinical negligence cover in the UK into the scope of the Regulated Activities Order 2001 ("RAO") as a regulated activity, and in addition, a PRA-regulated activity subject to prudential supervision by the PRA.

5.20 One option would be that from the effective date of the legislative changes, any organisation offering a product that is intended to cover liability in respect of clinical negligence would need to be appropriately authorised to do so by the PRA and FCA. The requirement to seek regulatory authorisation would only apply to organisations that continued to sell indemnity products after the effective date and therefore this option would not require providers of discretionary clinical negligence indemnity to seek regulatory authorisation for indemnity offered before this date, save to the extent that such providers continued to renew or sell new indemnity products after the effective date.

5.21 Introducing changes via the RAO would differ from amendments to professional standards legislation as it could potentially involve regulation of the sale of discretionary indemnity by indemnity providers in the UK to healthcare professionals abroad. If indemnity providers continue or begin to sell discretionary indemnity abroad in a scenario where Government introduced changes solely to professional regulation, then there may be a risk of losses from this overseas business impacting the solvent run-off of existing liabilities of these indemnity providers in the UK (if the indemnity providers choose and are permitted to continue to run-off their existing liabilities on an unregulated basis).

5.22 Introducing changes solely via amendments to financial regulation is not a preferred option for Government at this stage, as it would not prevent regulated healthcare professionals in the UK from obtaining discretionary clinical negligence indemnity from overseas providers operating from jurisdictions where clinical negligence cover can be provided on an unregulated basis.

## **c) A combination of amendments to healthcare professional standards legislation and financial legislation**

- 5.23 The Government is also considering whether a combination of amendments to professional standards and financial legislation would meet the Government's stated policy objectives.
- 5.24 Any of these proposed changes (professional regulation, financial regulation, or a combination of both) would require further consultation on the draft legislation which would affect the proposed amendments.
- 5.25 These arrangements could be accompanied by a lead-in time and/or transitional arrangements. It may also be possible for indemnity providers to continue to run-off their historic liabilities on an unregulated basis for a period, while selling a regulated product through another entity within their corporate group (e.g. through the establishment of separate subsidiaries under a mixed-activity insurance holding company).
- 5.26 These legislative changes, through either or both routes would apply across the UK. The regulation of financial services under the FSMA is of UK extent, and the devolved position for professional regulation is set out below:
- In Wales, professional regulation is a matter reserved to the UK Parliament;
  - In Scotland, only the professions that have been created since the devolution settlement are a devolved matter. This means that the General Dental Council, the General Pharmaceutical Council, and the Health and Care Professions Council are accountable to the Scottish Parliament as well as to the UK Parliament in respect of certain professional groups that have become regulated since the Scotland Act 1998 (for example, dental technicians and dental nurses);
  - In Northern Ireland, health regulation is a transferred matter, but the only piece of legislation specific to Northern Ireland is the Pharmacy (Northern Ireland) Order 1976.

## **Potential benefits**

- 5.27 If regulated healthcare professionals in the UK (not covered by a state-backed scheme) were required to hold cover with regulatory supervision in respect of incidents of negligence occurring after a specified future date, it would remove the possibility of a regulated healthcare professional holding the benefit of a discretionary clinical

negligence indemnity arrangement. This would remove associated risk that an indemnity provider may exercise its discretion not to support a member. This would be subject to the regulatory perimeter and if a decision was made that regulated indemnity would need to be written on an insurance basis. Unlike discretionary indemnity, a contract of insurance creates an enforceable contractual agreement between the insurer and healthcare professional that obliges the provider to pay out for incidents that occur, in accordance with the terms of the contract.

- 5.28 Subject to meeting certain minimum thresholds, all UK providers selling clinical negligence indemnity arrangements to regulated healthcare professionals would be regulated by the PRA under the Financial Services and Markets Act 2000. The PRA currently exercises supervisory responsibility and takes action in accordance with its objectives to promote the safety and soundness of PRA-authorized persons, and to protect insurance policyholders. The FCA regulates conduct and polices the regulatory perimeter. Subject to its objectives being tailored for the providers of clinical negligence indemnity, prudential regulation by the PRA may reduce the potential risk for an indemnity provider to restrict the support given to healthcare professionals, and therefore compensation for patients. Increased regulatory oversight is likely to provide greater certainty that financial promises made by such institutions are met.
- 5.29 Regulated healthcare professionals not covered by a state-backed scheme would only be able to purchase clinical negligence cover from regulated providers who are required to disclose their financial position and are subject to reporting and oversight by their relevant regulator. Transparency is one of the pillars of financial regulation and requires regulated entities to publish certain information about their financial position and to deal in an open and co-operative manner with their regulators, disclosing all relevant information of which a regulator would reasonably expect notice.
- 5.30 If writing contracts of insurance, indemnity providers would be required to follow the FCA's Principles for Business, including in relation to treating customers fairly. This may reduce the risk that healthcare professionals are treated unfairly by their indemnity providers, for example, if they are not provided with the full information about the nature of their cover, or if this cover is withdrawn.
- 5.31 As regulated healthcare professionals would only be able to purchase a regulated product, this may encourage competition and innovation in the clinical negligence cover on offer. At present, as only insurance providers have to comply with prudential regulation and pay Insurance Premium Tax, they may not be able to compete with providers of discretionary clinical negligence indemnity on prices. While there could be an overall higher cost of cover with regulated products, increased price competition in the market may limit the extent of prices rises.

## Potential risks

- 5.32 There may be uncertainty over how indemnity providers would adjust to changes in professional and/or financial regulation. If providers of clinical negligence cover chose to seek authorisation under FSMA, this would necessitate a change in business model and approach, particularly around compliance with regulation that would incur an additional cost. The extent of this cost would depend on the business model or approach chosen. Alternatively, there is also the possibility that existing providers of discretionary indemnity choose not to or face difficulties in continuing to provide indemnity. Depending on the market response and the pace of the transition, there is a potential that there could be some gaps in coverage. It may also take time for new or existing market participants to enter the market or expand their operations. The introduction of changes to regulation could therefore be accompanied by a lead-in time and/or transitional arrangements to mitigate these risks. One option could be that indemnity providers could prudently run-off their historic liabilities on a discretionary basis for a period, while, subject to authorisation, selling a regulated product through the establishment of separate subsidiaries under a mixed-activity insurance holding company.
- 5.33 As providers of discretionary clinical negligence indemnity would have to comply with regulation in order to continue to sell clinical negligence cover to regulated healthcare professionals, this could lead to an overall higher cost of cover for the professional. This would need to be balanced against the arguably greater financial security of a regulated product (see Annex B, para 7.25). The Government will closely consider the potential impacts on the wider healthcare workforce of changes in indemnity costs.
- 5.34 With contractual cover, regulated healthcare professionals need to ensure that the scope and risk of their practice is reflected in the terms and conditions of their contract of insurance – that it does not exclude any relevant activities and that the limit of cover is appropriate. The consultation asks whether the Government should specify a minimum standard of insurance for regulated healthcare professionals.
- 5.35 If a regulated healthcare professional purchases a claims-made or claims-paid policy or indemnity arrangement, then they will need to purchase run-off cover to be covered for any claims arising after the period of their policy. The majority of insurers offering clinical negligence cover currently offer this on a claims-made basis. More recently MDOs, however, have started to offer discretionary indemnity on a claims-made and claims-paid basis, so the number of regulated healthcare professionals who are required to obtain run-off cover will increase in accordance with movements to such products in any event. There is also the risk that patients may not be appropriately compensated for a future claim if healthcare professionals were not to take out appropriate run-off cover.



## Conclusion

5.36 The key advantage of option (ii) is that it would ensure that regulated healthcare professionals hold clinical negligence cover with appropriate oversight from the established financial regulators. Depending on the level of regulatory supervision, this would address the risks identified earlier in this document whereby healthcare professionals may not have a sufficiently enforceable right to cover, hold cover that is not supported by sufficient financial resources against the risk of potential claims, and have transparency into the terms and conditions of their cover. The Government would need to consider the potential market impacts and cost impacts for healthcare professionals. **The Government's preferred option at this stage is to ensure that all regulated healthcare professionals in the UK not covered by a state-backed indemnity scheme hold appropriate clinical negligence cover that is subject to appropriate supervision, in the case of UK insurers by the FCA and PRA.**

## 6. Consultation questions

- 6.1 What are your views on the proposed options for meeting the Government's policy objectives (please see paragraph 4.1)?
- 6.2 What are your views on the potential costs and benefits of these options, for example the familiarisation and administrative costs for individuals, businesses, and other groups, in complying with potential changes to regulation?
- 6.3 Are there any other options that the Government should consider?
- 6.4 Do you agree with the Government's preferred option (ii), set out from paragraph 5.15, of ensuring that all regulated healthcare professionals in the UK hold appropriate clinical negligence cover that is subject to appropriate supervision by the FCA and PRA?
- 6.5 Do you have further insight or data into the types of indemnity/insurance cover held by healthcare professionals?

### If Government pursues option (ii)

- 6.6 In order to achieve this aim, what would be the benefits or implications of introducing regulation via:
- a) changing professional standards so that professionals have to hold a regulated product in order to practise;
  - b) changing financial regulation so that any organisation offering clinical negligence cover would need to be authorised to do so;
  - c) changing both financial and professional regulation.
- 6.7 Do you have a view on when regulations should come into force and should these involve a transitional period, considering the potential impact on indemnity providers and healthcare professionals?
- 6.8 Are there any measures that could mitigate the potential risks to introducing regulation as set out in paragraphs 5.32-5.35 (in terms of a stable transition for regulated healthcare professionals and indemnity providers, mitigating potential cost impacts, and run-off cover)?

## Appropriate clinical negligence cover

- 6.9 Specifically, on the transition risk, are there any measures that could support the run-off of indemnity providers' existing liabilities on a discretionary basis, and given the potential interaction with overseas business set out in paragraph 5.21?
- 6.10 Specifically given the potential risk with claims-made and claims-paid policies and indemnity arrangements as set out in 5.35, should Government specify the type of insurance or regulated product required for regulated healthcare professionals? This could take the form of a) claims-occurring cover, b) claims-made cover, c) claims-made cover with built-in run-off cover on either death or retirement from clinical practice, or d) a combination of these.
- 6.11 Related to the above, should the Government and/or the professional healthcare regulators specify a minimum standard of insurance or regulated cover that should be required for regulated healthcare professionals (for example, a minimum level of cover for each claim and in the aggregate, depending on the regulated healthcare professional)?
- 6.12 Are there any equality issues that arise (positive or negative) in relation to each of the options but, in particular, in relation to the Government's preferred option (ii) which is set out from paragraph 5.15? In particular:
- 6.13 Is there any discriminatory impact (direct or indirect) arising from any of the proposed options that would engage the Equality Act 2010 and Section 75 of the Northern Ireland Act 1998?
- 6.14 What is the impact, if any, on any group of persons who share one or more of the protected characteristics set out in section 149 of the Equality Act 2010 when compared with persons who do not share the protected characteristic(s)? Section 149 of the Equality Act 2010 is set out in full in Annex C.
- 6.15 What are the potential consequences to the conduct of clinical research of the proposals set out in this document?

## 7. Responding to the consultation

- 7.1 This document launches a consultation on options related to appropriate clinical negligence cover for healthcare professionals and strengthening patient recourse.
- 7.2 The closing date for the consultation is 28 February 2019. To complete the online consultation response document, go to: <https://consultations.dh.gov.uk/resolution-patient-experience-and-maternity/indemnity-regulation> Alternatively, to respond via email, email to: [clinicalnegligenceregulationconsultation@dhsc.gov.uk](mailto:clinicalnegligenceregulationconsultation@dhsc.gov.uk)
- 7.3 To respond to the consultation via post, please send responses to:
- Appropriate Clinical Negligence Cover Consultation
- Acute Care and Quality Directorate, Fifth Floor
- Department of Health and Social Care
- 39 Victoria Street, London
- SW1H 0EU
- 7.4 It will help us to analyse the responses if respondents fill in the online 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 in pdf format.
- 7.5 The consultation is being run as far as is practical in accordance with the Cabinet Office Consultation Principles: <https://www.gov.uk/government/publications/consultation-principles-guidance>
- 7.6 We manage the information you provide in response to this consultation in accordance with the Department of Health and Social Care's Information Charter: <https://www.gov.uk/government/organisations/department-of-health-and-social-care/about/personal-information-charter>
- 7.7 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 2018 (DPA) and the General Data Protection Regulation (GDPR), and the Environmental Information Regulations 2004).
- 7.8 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 which public authorities

## Appropriate clinical negligence cover

must comply with 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, as well as any exemptions that may apply in relation to the information provided, 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.

- 7.9 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.
- 7.10 A summary of the responses to this consultation will be made available before or alongside any further action and will be placed on the GOV.UK website ([www.gov.uk/dhsc](http://www.gov.uk/dhsc)).

# Annex A: Healthcare professional regulatory bodies and current definitions of appropriate cover

Regulatory body	Acronym	Professions regulated	No. of registrants (including premises) 2015/2016	Current definition of appropriate cover
General Chiropractic Council	GCC	Chiropractors	3,109	An insurance policy or indemnity arrangement with a minimum amount of cover of £5 million.
General Dental Council	GDC	Dentists Clinical dental technicians Dental hygienists Dental nurses Dental technicians Dental therapists Orthodontic therapists	108,209	An insurance policy or indemnity arrangement appropriate to the risks and scope of their practice.
General Medical Council	GMC	Medical practitioners	273,761	An insurance policy or indemnity arrangement appropriate to the risks and scope of their practice.
General Optical Council	GOC	Optometrists  Dispensing opticians  Student optometrists  Student dispensing	29,136	An insurance or indemnity policy.

Appropriate clinical negligence cover

Regulatory body	Acronym	Professions regulated	No. of registrants (including premises) 2015/2016	Current definition of appropriate cover
		opticians Optical businesses		
General Osteopathic Council	GOsC	Osteopaths	5,102	Indemnity arrangements with a minimum amount of cover of £5 million.
General Pharmaceutical Council	GPhC	Pharmacists in Great Britain Pharmacy technicians in Great Britain Pharmacy business premises in Great Britain	89,377	An insurance policy or indemnity arrangement appropriate to the risks and scope of their practice.
Health and Care Professions Council	HCPC	Arts therapists Biomedical scientists Chiropodists / podiatrists Clinical scientists Dietitians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists	341,745	An insurance policy or indemnity arrangement appropriate to the risks and scope of their practice.

Regulatory body	Acronym	Professions regulated	No. of registrants (including premises) 2015/2016	Current definition of appropriate cover
		Paramedics Physiotherapists Practitioner psychologists Prosthetists / orthotists Radiographers Social workers in England Speech and language therapists		
Nursing and Midwifery Council	NMC	Nurses Midwives Nursing associates from 28 January 2019	692,550	An insurance policy or indemnity arrangement appropriate to the risks and scope of their practice.
Pharmaceutical Society of Northern Ireland	PSNI	Pharmacists in Northern Ireland Pharmacy business premises in Northern Ireland	2,852	An insurance policy or indemnity arrangement appropriate to the risks and scope of their practice.

**Note:** Most of the regulatory bodies cover the whole of the UK. The exception to this is the GPhC which regulates pharmacists and pharmacy technicians in England, Scotland and Wales, and the PSNI which regulates pharmacists in Northern Ireland. Additionally, the GPhC and the PSNI regulate pharmacy business premises and the GOC regulates optical businesses. The PSNI also has a professional leadership function that the other regulators do not.



# Annex B: Summary of impact of the consultation options

7.11 The potential costs, benefits, and risks of both consultation options are set out within the body of the consultation document. The overall impact of these options is summarised below. The Department welcomes views on any other implications to inform and update the following analysis:

## Option 1: Maintaining the existing legislation and arrangements related to clinical negligence cover, ‘do nothing’

7.12 This option would involve regulated healthcare professionals practising in the UK not covered by state-backed indemnity schemes continuing to be allowed to hold the benefit of discretionary clinical negligence indemnity arrangements as permitted in current professional standards legislation.

7.13 **Flexibility of cover:** Discretionary indemnity may offer indemnity providers greater flexibility to support their members, as there is no explicit limit on the extent of financial support offered (provided that the indemnity provider has the adequate financial resources), or on the activities that may be supported.

7.14 **Potential risk of discretion exercised not to support a regulated healthcare professional:** While the flexibility of discretionary indemnity may be beneficial in some circumstances, a risk remains, however, that a member could be refused assistance if their provider, for any reason including financial difficulty of the provider, chooses not to support the member in defending a claim against them, or to pay all or a proportion of an award of compensation (and any legal costs) made by a court agreed by way of settlement. Where the provider does not meet the claim in full, the healthcare professional would be left without the backing of the provider and therefore be personally exposed for any compensation or costs which are payable. A healthcare provider may also be exposed for any compensation or costs if they are vicariously liable for the incident of clinical negligence, potentially reducing their financial resources for delivering care.

7.15 **Absence of prudential regulation requirements:** The absence of regulatory requirements for the provision of discretionary indemnity in terms of reserving adequately to meet expected claims raises the risk that providers may not be able to meet the cost of claims in the future, for example, because of an external development or changes in the market. This may increase the risk of an indemnity provider exercising

their discretion not to support their members, with patients losing out on potential compensation as a result, or the risk of insufficient and/or unaffordable clinical negligence cover in the market.

- 7.16 **Affordability of cover:** The absence of regulatory requirements for providers of discretionary indemnity to reserve adequately to meet their liabilities and hold sufficient capital, and the fact that they are not subject to paying Insurance Premium Tax or Financial Services Compensation Scheme levies, may enable these providers to offer more affordable cover to healthcare professionals than insurance companies, particularly as clinical negligence costs are rising.
- 7.17 **Absence of oversight from established financial regulators:** Under current arrangements, providers of discretionary clinical negligence indemnity are not subject to FCA or PRA oversight or regulatory reporting requirements in respect of this cover, as regulated insurance companies are for contracts of insurance. This may increase the risk that an indemnity provider cannot meet the cost of expected claims, and healthcare professionals are left without sufficient financial protection. It may not also provide healthcare professionals with reassurance about the extent of their financial protection, or conversely, exposure, and the public and patients with confidence in their recourse for clinical negligence.
- 7.18 **Awareness of cover may be uncertain:** It is not clear how far regulated healthcare professionals are currently informed and aware of the terms and scope of the cover provided by discretionary indemnity arrangements. This may relate to how the discretionary indemnity works, including how and when discretion may be exercised; what will be covered, and whether the indemnity operates on a claims-made, claims-paid, or claims-occurring basis. This is in comparison with a contract of insurance that sets out specific terms and conditions under which a policyholder is covered, and is subject to financial conduct regulation.

## **Option 2: Legislative change by way of secondary legislation to ensure that regulated healthcare professionals in the UK (not covered by a state-backed scheme) hold appropriate clinical negligence cover that is subject to appropriate supervision by the FCA and PRA.**

- 7.19 This could be achieved by a) amendments to professional regulation to require regulated healthcare professionals to purchase insurance cover from an insurance provider regulated by the FCA and PRA, b) bringing clinical negligence indemnity into the scope of the FSMA (therefore subject to regulatory oversight from the FCA, and further, make the provision of clinical negligence indemnity a PRA-regulated activity subject to prudential regulation by the PRA), c) a combination of both approaches.

- 7.20 **Sufficiently enforceable cover:** Regulated healthcare professionals in the UK not covered by a state-backed scheme would be required to hold cover with regulatory supervision in respect of incidents of negligence occurring after a specified future date. Subject to the regulatory perimeter, this would remove the possibility of a regulated healthcare professional holding the benefit of a discretionary clinical negligence indemnity arrangement and the associated risk that an indemnity provider may exercise its discretion not to support a member. Unlike discretionary indemnity, a contract of insurance creates an enforceable contractual agreement between the provider and healthcare professional that obliges the provider to pay out for incidents that occur under the terms of the contract.
- 7.21 **Financially sufficient cover:** Subject to meeting certain minimum thresholds, all UK providers selling clinical negligence indemnity to regulated healthcare professionals would be regulated by the PRA under the Financial Services and Markets Act 2000. The PRA currently exercises supervisory responsibility and takes action in accordance with its objectives to promote the safety and soundness of PRA-authorized persons, and to protect insurance policyholders. The FCA regulates conduct and polices the regulatory perimeter. Subject to its objectives being tailored, prudential regulation by the PRA may reduce the potential risk for an indemnity provider to restrict the support given to healthcare professionals, and therefore compensation for patients.
- 7.22 **Financial conduct requirements:** The providers of cover to regulated healthcare professionals would be required to follow the FCA's supervisory responsibility in relation to treating customers fairly. This may reduce the risk that healthcare professionals are treated unfairly by their indemnity providers, for example, if they are not provided with the full information about the nature of their cover, or if this cover is withdrawn.
- 7.23 **Competition and innovation:** As regulated healthcare professionals would only be able to purchase a regulated product, this may encourage competition and innovation in the clinical negligence cover on offer. At present, as only insurance providers have to comply with prudential regulation, they may not be able to compete with providers of discretionary clinical negligence indemnity on prices.
- 7.24 **Risk of market transition:** There may be uncertainty over how indemnity providers would adjust to changes in professional and/or financial regulation. If providers of clinical negligence cover chose to seek authorisation as under FSMA, this would necessitate a change in business model and approach, particularly around compliance with regulation that would incur an additional cost. The extent of this cost will depend on the business model or approach chosen. Alternatively, there is also the possibility that existing providers of discretionary indemnity choose not to or face difficulties in continuing to provide cover. Depending on the market response and the pace of the transition, there is a potential that there could be some gaps in coverage. It may also take time for new or existing insurance companies to enter the market or expand their operations. The introduction of changes to regulations could be accompanied by a lead-in time and/or transitional arrangements to mitigate these risks. It may also be

possible for indemnity providers to prudently run-off their historic liabilities on a discretionary basis for a period, while, subject to authorisation, selling a regulated product through another entity within their corporate group (e.g. through the establishment of separate subsidiaries under a mixed-activity insurance holding company).

- 7.25 **Overall higher cost of clinical negligence cover:** As providers of discretionary clinical negligence indemnity would have to comply with regulation in order to continue to sell clinical negligence cover to regulated healthcare professionals, this could be reflected in an overall higher cost of cover for the professional. This would need to be balanced against the arguably greater financial security of a regulated product. Under an insurance model, (and subject to the terms of the policy) there is a higher chance of a policyholder receiving payment for a claim than under a discretionary model because of 1) the elimination of discretion and 2) the creation of a contractual contingent obligation to pay. However, an insurance product may be subject to any caps or exclusions set out in the terms and conditions of the product. If an insurer fails to pay, policyholders would have access to the Financial Services Compensation Scheme, providing them with greater financial protection. The Government will closely consider the potential impacts on the wider healthcare workforce of changes in indemnity costs.
- 7.26 **Compliance with terms and conditions of contracts of insurance:** With contractual cover, regulated healthcare professionals need to ensure that the scope and risk of their practice is reflected in the terms and conditions of their contract of insurance – that it does not exclude any relevant activities and that the limit of cover is appropriate. The consultation asks whether the Government should specify a minimum standard of insurance or regulated product for regulated healthcare professionals.

## Annex C: Equality Act - Section 149

(1) A public authority must, in the exercise of its functions, have due regard to the need to—  
eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;

advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;

foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

(2) A person who is not a public authority but who exercises public functions must, in the exercise of those functions, have due regard to the matters mentioned in subsection (1).

(3) Having due regard to the need to advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it involves having due regard to the need to—

remove or minimise disadvantages suffered by persons who share a relevant protected characteristic that are connected to that characteristic;

take steps to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it;

encourage persons who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such persons is disproportionately low.

(4) The steps involved in meeting the needs of disabled persons that are different from the needs of persons who are not disabled include steps to take account of disabled persons' disabilities.

(5) Having due regard to the need to foster good relations between persons who share a relevant protected characteristic and persons who do not share it involves having due regard to the need to—

tackle prejudice, and

promote understanding.

(6) Compliance with the duties in this section may involve treating some persons more favourably than others; but that is not to be taken as permitting conduct that would otherwise be prohibited by or under this Act.

(7) The relevant protected characteristics are—

- age;
- disability;
- gender reassignment;
- pregnancy and maternity;
- race;
- religion or belief;
- sex;
- sexual orientation;
- marriage and civil partnership.

(8) A reference to conduct that is prohibited by or under this Act includes a reference to—

a breach of an equality clause or rule;

a breach of a non-discrimination rule.

(9) Schedule 18 (exceptions) has effect.

# Glossary

**Claims-made cover:** A claims-made insurance policy or discretionary indemnity provides coverage in respect of claims brought against a healthcare professional arising from acts that occurred during the policy or membership period, provided that the resulting claim is made and reported to the insurer or indemnity provider prior to the end of this period. Once the policy or membership has lapsed (for example, if the healthcare professional switches insurance or indemnity provider or retires from practice), no cover will be offered in respect of any new claims not reported during the policy or membership period. The healthcare professional will therefore need to purchase run-off cover to remain protected against any further claims that were accrued but not reported during their policy or membership period.

**Claims-paid cover:** A claims-paid insurance policy or discretionary indemnity provides cover on the same basis as claims-made cover, save that claims will only be met if they are settled (as well as accrued and reported) during the policy or membership period. Healthcare professionals with claims-paid cover will therefore also need to purchase run-off cover after the expiry of their policy or membership period, in order to remain protected against any claims that accrued but were not settled during this period.

**Claims-occurring (or occurrence-based) cover:** A claims-occurring insurance policy or discretionary indemnity provides coverage for incidents of negligence which occur during the policy or membership period, regardless of when the claim for that negligence is made.

**Clinical negligence:** Clinical negligence arises where there is a breach of the common law duty of care owed to a patient by members of the healthcare professions or by others acting on their decisions or judgements, or omitting to act, which causes harm or physical injury to a patient. If a patient has suffered harm or injury as a result of clinical negligence, the patient or their representative may make a claim for damages against the clinicians or their employers.

**Clinical Negligence Scheme for Trusts (CNST):** This scheme provides clinical negligence cover to providers of NHS services, NHS commissioners, and Health Arm's Length Bodies for claims arising from incidents involving clinical negligence. Contributions are collected from members to make settlements and administer claims on their behalf.

**Damages:** In the context of clinical negligence, damages refer to the compensation to the patient for the damage, loss, or injury they have suffered as result of the negligence of a healthcare professional. The purpose of damages is to put the patient in the same position as they would have been but for the injury, loss, or damage, so far as the payment of a sum of money can do so.

**Discretionary indemnity:** Clinical negligence indemnity where legal and financial assistance is provided at the discretion of the provider i.e. not backed by an insurance contract between the healthcare professional and the provider.

**Duty of care:** Where a healthcare professional has assumed some sort of responsibility for a patient's care, the law imposes a duty on the healthcare professional to act in accordance with the relevant standard of care. This is generally assessed to be the standard expected of an 'ordinarily competent practitioner' performing that task or role. Regulated healthcare professionals also hold a professional duty of care to follow standards and conduct set by their professional regulator.

**Financial conduct regulation:** Conduct regulation requires financial firms to treat their customers fairly, and is based on the principles that financial markets should be honest, fair, and effective so that consumers get a fair deal. The Financial Conduct Authority (FCA) is responsible for conduct regulation in the UK.

**Indemnity:** Compensation for a loss or liability which one person has incurred. Contractual indemnity is a contractual obligation to compensate for some defined loss or damage, by making a money payment.

**Insurance Premium Tax:** Insurance Premium Tax is a tax on general insurance premiums. There are two rates: standard 12%, and a higher rate 20% for travel insurance, certain insurance when sold with mechanical/electrical appliances, certain insurance when sold with some motor vehicles.

**NHS Constitution:** The NHS Constitution for England sets out rights for patients, public and staff. It outlines NHS commitments to patients and staff, and the responsibilities that the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively. All NHS bodies and private and third sector providers supplying NHS services are required by law to take account of the Constitution in their decisions and actions.

<https://www.gov.uk/government/publications/the-nhs-constitution-for-england>

**NHS Resolution:** NHS Resolution is an Arm's Length Body of the Department of Health and Social Care with the purpose of providing expertise to the NHS on resolving concerns fairly, sharing learning for improvement, and preserving resources for patient care. The main bulk of NHS Resolution's workload is handling negligence claims on behalf of the members of its indemnity schemes (including the Clinical Negligence Scheme for Trusts): NHS organisations and independent sector providers of NHS care in England.

**Occurrence-based cover:** See 'Claims-occurring' cover.

**Personal Injury Discount Rate (PIDR):** The PIDR is a figure used in calculating how much defendants should pay claimants in cases of life-changing injury. The calculation of a lump sum for future financial loss includes applying a discount rate which represents the rate of return that claimants are expected to earn when investing it. The discount rate is intended to ensure that the opportunity to invest does not result in either over- or under-compensation.

**Professional regulatory bodies:** The organisations responsible for protecting the public by: i) setting the standards of behaviour, competence, and education that health professionals must



## Appropriate clinical negligence cover

meet, ii) dealing with concerns from patients, the public and others about health professionals who are unfit to practice because of poor health, misconduct, or poor performance, iii) keeping registers of health professionals who are fit to practice in the United Kingdom. The regulators have powers to initiate proceedings to prevent professionals from practising and to remove professionals from their registers if they consider this to be in the best interests of the public.

**Prudential regulation:** Prudential regulation rules require financial firms to hold sufficient capital and have adequate risk controls in place. UK insurers are closely supervised by the Prudential Regulation Authority (PRA) so that the PRA can intervene if they are not being run in a safe or sound way such as to protect policyholders adequately.

**Registration:** Those healthcare professionals practising a statutorily regulated profession must apply to join the appropriate regulator's register. It is a criminal offence for an individual to practice a statutorily regulated profession without being listed on the appropriate register.

**Regulated Activities Order (RAO)/Financial Services and Markets Act (FSMA):** The Financial Services and Markets Act 2000 (FSMA 2000) governs the regulation of financial services and markets in the UK. The Financial Services and Markets Act 2000 (Regulated Activities) Order 2001, SI 2001/544 (RAO) sets out a list of specified kinds of activities and investments that are considered to be a regulated activity for the purposes of FSMA 2000. The FSMA (PRA-regulated Activities) Order 2013 specifies the specific regulated activities that are subject to prudential regulation by the PRA.

**Regulated healthcare professional:** A healthcare professional regulated by statutory provision who is required to register with the appropriate regulatory body and to meet the standards of practice set by those organisations. There are nine regulatory bodies responsible for regulating 32 professions in the UK, these are independent bodies overseen and scrutinised by the Professional Standards Authority for Health and Social Care (PSA). All healthcare professionals who wish to practise in the UK are legally required as a condition of registration with the professional regulator (or in the case of doctors, as a condition of the grant of a licence to practise), to hold appropriate clinical negligence cover for the risks of their practice, covering the costs of defending clinical negligence claims and damages awarded to patients.

**Run-off cover:** Run-off cover provides cover for claims where the adverse incident has already occurred but has not yet been reported prior to the expiry of the policy or membership period to which the run-off cover relates. The cover could be renewed annually or, for a single payment, cover all past incidents whenever they are reported in the future. This type of cover is required when a member of an MDO or policyholder of an insurer has either claims-made cover or claims-paid cover and either switches indemnifier or ceases to practise.

**Solvency II:** Solvency II is a European Union directive, implemented in UK legislation, that sets out regulatory requirements for insurance firms and groups, covering financial resources, governance and accountability, risk assessment and management, supervision, reporting, and public disclosure.

# References

---

- <sup>i</sup> National Audit Office. Managing the cost of clinical negligence in Trusts. [www.nao.org.uk/wp-content/uploads/2017/09/Managing-the-costs-of-clinical-negligence-in-trusts.pdf](http://www.nao.org.uk/wp-content/uploads/2017/09/Managing-the-costs-of-clinical-negligence-in-trusts.pdf) (September 2017, accessed July 2018)
- <sup>ii</sup> Public Accounts Committee. Managing the cost of clinical negligence in trusts. <https://publications.parliament.uk/pa/cm201719/cmselect/cmpubacc/397/39702.htm> (December 2017, accessed July 2018).
- <sup>iii</sup> Independent Inquiry into the issues raised by Paterson: Terms of Reference. <https://www.patersoninquiry.org.uk/terms-of-reference/> (accessed July 2018).
- <sup>iv</sup> Independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/216297/dh\\_1174\\_57.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216297/dh_1174_57.pdf) (June 2010, accessed July 2018).
- <sup>v</sup> H. Beety, S. Von Toerne, S. Spender, E. Miskin-Garside v NMC, 2017 [www.nmc.org.uk/globalassets/sitedocuments/press/approved-judgment---rbeety-and-ors-v-nmc-and-ors.pdf](http://www.nmc.org.uk/globalassets/sitedocuments/press/approved-judgment---rbeety-and-ors-v-nmc-and-ors.pdf) (accessed July 2018).
- <sup>vi</sup> Financial Conduct Authority. FCA Handbook: PRIN 2.1 The Principles. [www.handbook.fca.org.uk/handbook/PRIN/2/1.html](http://www.handbook.fca.org.uk/handbook/PRIN/2/1.html) (January 2018, accessed July 2018).
- <sup>vii</sup> UK Policy Framework for Health and Social Care Research <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/> (accessed October 2018).
- <sup>viii</sup> Prudential Regulation Authority. The Prudential Regulation Authority's approach to insurance supervision. P25. [www.bankofengland.co.uk/-/media/boe/files/prudential-regulation/approach/insurance-approach-2016.pdf](http://www.bankofengland.co.uk/-/media/boe/files/prudential-regulation/approach/insurance-approach-2016.pdf) (March 2016, accessed July 2018).
- <sup>ix</sup> Department of Health, Republic of Ireland. Press release: Settlement Agreement between Dr James Reilly, TD, Minister for Health and the Medical Defence Union (MDU). <https://health.gov.ie/blog/press-release/settlement-agreement-between-dr-james-reilly-td-minister-for-health-and-the-medical-defence-union-mdu/> (December 2012, accessed July 2018).
- <sup>x</sup> MDU Memorandum and Articles of Association <https://www.themdu.com/about-mdu/memorandum-and-articles-of-association>, MPS Memorandum and Articles of Association [https://www.medicalprotection.org/docs/default-source/pdfs/financial-information/mps\\_memoarts.pdf?sfvrsn=14](https://www.medicalprotection.org/docs/default-source/pdfs/financial-information/mps_memoarts.pdf?sfvrsn=14); MDDUS Articles of Association <https://www.mddus.com/about-us/corporate-governance/mddus-corporate-documents>, [All accessed November 2018].
- <sup>xi</sup> The Department for Health and Social Care. The NHS Constitution for England. <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england> (Updated October 2015, accessed October 2018)
- <sup>xii</sup> On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

<sup>xiii</sup> I) NHS Resolution. Press release: NHS Resolution presses ahead with mediation as litigation decreases but claims costs continue to rise <https://resolution.nhs.uk/2018/07/12/nhs-resolution-presses-ahead-with-mediation-as-litigation-decreases-but-claims-costs-continue-to-rise/> (12 July 2018, accessed November 2018); II) MPS Press release: Medical Protection Society calls on Government not to water down the Civil Liabilities Bill, <https://www.medicalprotection.org/uk/articles/medical-protection-society-calls-on-government-not-to-water-down-the-civil-liability-bill> (4 September 2018, accessed November 2018). III) MDU Press Release: Urgent Action needed to curb compensation pay outs, <https://www.themdu.com/press-centre/press-releases/urgent-action-needed-to-curb-compensation-payouts-says-mdu> (13 July 2018, accessed December 2018); IV) MDDUS Press Release: Five Key Messages to address discount rate reform, <https://www.mddus.com/about-us/notice-board/2018/april/five-key-messages-to-address-discount-rate-reform> (27 April 2018, accessed December 2018).

<sup>xiv</sup> Civil Liability Bill [HL] Explanatory Notes, p.4.: <https://publications.parliament.uk/pa/bills/lbill/2017-2019/0090/18090en.pdf>.

<sup>xv</sup> Financial Conduct Authority. Fair treatment of customers. [www.fca.org.uk/firms/fair-treatment-customers](http://www.fca.org.uk/firms/fair-treatment-customers) (February 2018, accessed July 2018).

<sup>xvi</sup> Department of Health and Social Care / Ipsos MORI. GP Indemnity survey (7th March-24th April 2018), to be published at the following link: <https://www.ipsos.com/ipsos-mori/en-uk/findings-general-practitioners-indemnity-survey>.

<sup>xvii</sup> Chiropractors Act 1994, Dentists Act 1984, Medical Act 1983, Opticians Act 1989, Osteopaths Act 1993, Pharmacy Order 2010, Health and Social Work Professions Order 2010, Nursing and Midwifery Order 2001, the Pharmacy (Northern Ireland) Order 1976.

© Crown copyright 2018

Published to GOV.UK in pdf format only.

Acute Care and Quality Directorate

[www.gov.uk/dhsc](http://www.gov.uk/dhsc)

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit [nationalarchives.gov.uk/doc/open-government-licence/version/3](http://nationalarchives.gov.uk/doc/open-government-licence/version/3)

Where we have identified any third-party copyright information you will need to obtain permission from the copyright holders concerned.