

EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CLINICAL NEGLIGENCE SCHEME FOR GENERAL PRACTICE) REGULATIONS 2019

2019 No. 334

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (the “Department”) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 These Regulations establish an indemnity scheme (the “Scheme”) for general practice that will be administered by the Secretary of State for Health and Social Care. The Scheme provides cover for future clinical negligence liabilities of general practitioners (“GPs”) and others working in general practice in respect of activities carried out for the purposes of the national health service (“NHS”) in England. The Regulations will come into force on 1st April 2019.

3. Matters of special interest to Parliament

Matters of interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England and Wales.
- 4.2 The territorial application of this instrument is England. The Regulations establish a Scheme to provide indemnity cover in respect of services or activities carried out for the purposes of the NHS in England. This includes not only primary medical services and other NHS services provided by GPs, (and others working in a general practice setting) in England but also services that are delivered outside of England (for example, in Wales in cross-border cases) where such services are delivered for the purpose of the NHS in England.

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and is not subject to parliamentary procedure, no statement is required.

6. Legislative Context

- 6.1 This instrument is being made to establish an indemnity scheme for general practice that will be administered by the Secretary of State. The Scheme will provide indemnity cover in respect of liabilities in tort (under the law of England and Wales) that arise in consequence of a breach of duty of care by a GP (or other person working in general practice) which results in physical injury or loss to a person. Claims made under the Scheme will consist of mainly clinical negligence claims. Liabilities within the scope of the Scheme are liabilities incurred on or after 1st April 2019.
- 6.2 Under section 71 of the NHS Act 2006, the Secretary of State may make regulations to establish a scheme to meet the liabilities of the persons and bodies specified in section 71(2) of that Act. This includes GPs and others providing NHS services as part of general practice. The consent of the Treasury is required to make the Regulations.

7. Policy background

What is being done and why?

Policy objectives and rationale

- 7.1 The policy objectives underpinning the Scheme established by the Regulations are to introduce a more stable and affordable system for indemnifying general practice in a way which:
- contributes to improving retention and recruitment in general practice, therefore increasing capacity and improving access to general practice services for patients;
 - meets the needs of current and future general practice staff;
 - offers value for money for taxpayers;
 - relieves the administrative burden of securing indemnity provision for NHS services from individual professionals; and
 - provides for such indemnity to continue to apply in respect of new ways of working and where new models of care are introduced.
- 7.2 The Scheme is being introduced to address concerns that have arisen about the rising costs to GPs of indemnity arrangements for NHS clinical negligence liabilities and the current market structure relating to the provision of GP indemnity arrangements. The purpose of introducing the Scheme is to secure more stable, affordable indemnity arrangements for general practice in relation to the NHS work they carry out.
- 7.3 All healthcare professionals are required, under various statutory provisions, to have appropriate indemnity or insurance arrangements in place before they are able, lawfully, to practise. Currently, the vast majority of GPs and other primary care healthcare professionals purchase such cover annually from medical defence organisations (MDOs) which are private companies that operate on a not-for-profit, mutual basis. Healthcare professionals who turn to MDOs for indemnity provision pay an annual, risk-based, subscription for membership of an MDO. Indemnity cover is provided by the MDOs as part of the membership arrangements and is provided on a discretionary basis. As the indemnity cover provided is discretionary, MDOs are not subject to the regulatory requirements governing the provision of financial services.

- 7.4 Some indemnity cover for NHS clinical negligence liabilities of GPs and others working in general practice is also currently provided by the commercial insurance industry but this is under a contract of insurance (i.e. not on a discretionary basis) that is regulated under the financial services legislation that governs the provision of insurance products.
- 7.5 Prior to the announcement of the state scheme, the cost of GPs' indemnity subscriptions had risen sharply over a number of years, by approximately 10% per annum. The rising cost of indemnity subscriptions has been cited as one of the reasons why GPs are reducing their hours, and if the trend continues, may create a further shortage of GPs. This can discourage GPs from taking up activity such as out of hours care, which the government or NHS may wish to encourage, and in relation to which subscription costs may be higher and increases more substantial.¹ Increases in the last two years are estimated to be over 10% in total.²
- 7.6 A review by NHS England and the Department of the GP indemnity market in 2016 found that inefficiency was not the cause of rising indemnity subscriptions in the current arrangements, but it did recognise the pressure on GPs caused by the rising costs of indemnity. Following the Review, additional one-off funding of £30m and £60m was made available by NHS England and paid to practices in 16/17 and 17/18.
- 7.7 The key policy objectives are therefore to create an indemnity system which contributes to improving retention and recruitment in general practice, meets the needs of current and future GPs, including new models of multi-disciplinary care involving the wider practice team; removes the burden of arranging indemnity cover for GPs; and provides value for money for taxpayers.
- 7.8 Separately from the work undertaken in developing a state indemnity scheme for general practice, the Department is reviewing policy on indemnity cover for healthcare professionals who will need to continue to purchase their own indemnity cover because they are not covered by existing or proposed state indemnity schemes. A public consultation was carried out between 6th December 2018 and 28th February 2019. Consultation documents can be found at:
<https://www.gov.uk/government/consultations/appropriate-clinical-negligence-cover>.

The Scheme

- 7.9 The Regulations establish a scheme to be known as the Clinical Negligence Scheme for General Practice. The Scheme provides indemnity cover for the clinical negligence liabilities of healthcare professionals and others working in general practice in respect of services provided as part of the NHS in England. The Regulations come into force on 1st April 2019.
- 7.10 GPs and others working in general practice will not need to make any payments into the Scheme in order to benefit from the indemnity provided under it. The default position is that, from 1st April 2019, the NHS clinical negligence liabilities of GPs and

¹ <https://www.england.nhs.uk/wp-content/uploads/2016/07/gp-indemnity-rev-summary.pdf>

² Page 32 https://www.ipsos.com/sites/default/files/ct/publication/documents/2019-01/18-009474-01_dhsc_gp_indemnity_research_2018_v2_public.pdf

other general practice workers (i.e. those incurred on or after 1 April 2019) will ‘automatically’ be covered by the indemnity provided under the Scheme.

- 7.11 As stated earlier, the Scheme will cover liabilities for clinical negligence arising from the activities of not only GPs but also of any other person working in a general practice setting (including locums, trainees, dispensing doctors, nurses and clinical pharmacists) who are involved in providing primary medical services under contractual arrangements made under Part 4 of the National Health Services Act 2006 “GP contracts”. Such contractual arrangements consist of general medical services (GMS) contracts, primary medical services (PMS) contracts or alternative provider medical services (APMS) contracts. This includes primary medical services provided under APMS contracts that are part of any integrated urgent care package (with the APMS contract being included in schedule 2L to the NHS standard contracts for the urgent integrated care).
- 7.12 The Scheme will also cover clinical negligence liabilities arising from the provision by general practice of other NHS services, including public health services under arrangements made with a local authority (but only if such services are provided as part of the NHS in England), NHS services commissioned directly from GPs by clinical commissioning groups or NHS trusts, such as ‘step-down’ care that is intended to assist hospital patients to return home. The intention is to provide a state indemnity scheme that covers GPs and others working in a general practice setting for all NHS activities they carry out in such settings.
- 7.13 The Scheme will not cover liabilities relating to any activity that is not connected to the provision of NHS services. The Scheme, therefore, does not cover liabilities arising from privately-funded healthcare or any other non-NHS funded healthcare such as voluntary (Good Samaritan/Good Neighbour) activities. In addition, it will not include cover for activities of GPs carried out for other government departments, for example for the Department of Work and Pensions as these services are not provided under the NHS. As the Scheme only applies to the activities of GPs or others working in a general practice setting, it will not cover any NHS primary care services provided by health professionals who are not providing such services in a general practice setting, for example, dentists, optometrists or community pharmacists.
- 7.14 General practice staff and others carrying out activities in a general practice setting will, therefore, need to take out separate indemnity to cover any such ‘out-of-scope’ activities. GPs and other healthcare professionals may also choose to continue to secure access to advice and assistance (including representation) in relation to professional regulatory and disciplinary matters, as such advice and assistance will not be provided under the Scheme.
- 7.15 The Scheme will cover future liabilities of general practice incurred on or after the 1st April 2019, i.e. the date on which the Regulations come into force. In relation to liabilities incurred before 1st April 2019 (existing liabilities), further work is being carried out with the intention that a state indemnity scheme is established to cover existing liabilities also.
- 7.16 The commencement date for the Regulations reflects the start of the funding year for the GP contractual arrangements (provision of primary medical services) made under Part 4 of the National Health Service Act 2006. GP contract holders are paid quarterly in advance, the first payment in each year being due on 1st April. Commencing the

Regulations on 1st April will avoid any unnecessary and disproportionate efforts that would be required to change the quarterly payment date for April.

- 7.17 The Regulations have an impact on: the business of the MDOs, which are the main providers of discretionary indemnity to general practice; commercial insurance companies and brokers, which provide/arrange some indemnity insurance for general practice; and general practices.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union

9. Consolidation

- 9.1 This instrument does not amend or consolidate any other instruments.

10. Consultation outcome

- 10.1 A public consultation on the proposals for the Scheme was not undertaken. Instead, throughout the development of the policy for the Scheme, the Department has engaged, on an ongoing basis, with key stakeholders affected by the proposed changes arising from the implementation of a state scheme, including the MDOs, GPs (via representative bodies, including the British Medical Association and the Royal College for General Practice), commercial insurers, representative bodies of other healthcare professionals operating in the primary care sector and NHS England.³ This engagement process included meetings and other communications with stakeholders to assist them in understanding the proposals made and to elicit their views before final decisions were made on the Scheme policy.
- 10.2 The Regulations apply only in relation to liabilities incurred in respect of services provided as part of the NHS in England. We will work with the Devolved Administrations to monitor any consequential impact in Wales, Northern Ireland and Scotland. The Welsh Government is in the process of establishing a similar state indemnity scheme for general practice in Wales.

11. Guidance

- 11.1 Guidance on the Scheme will be published in advance of the 1st April 2019.

12. Impact

- 12.1 A summary impact assessment has been produced for publication alongside the regulations. The full version of the impact assessment has not been published as it contains legally privileged, confidential and commercially sensitive information - including information that, if disclosed, is likely to prejudice commercial interests.
- 12.2 The Regulations have an impact on the business of the MDOs, which are the main providers of discretionary indemnity to general practice; commercial insurance companies and brokers, which provide / arrange some indemnity insurance for general practice; and general practices.

³ NHS England is the National Health Service Commissioning Board, a statutory body corporate established under section 1H of the National Health Service Act 2006.

- 12.3 As explained in paragraph 7.8, the Department is reviewing policy on indemnity cover for healthcare professionals (dentists, private doctors, etc) who will need to continue to purchase their own indemnity cover because they are not covered by existing or proposed state indemnity schemes. There is no impact on charities or voluntary bodies.
- 12.4 In respect of any impact on the public sector, although GPs are independent contractors (i.e. not NHS employees), the costs of GP indemnity for the NHS activities covered by these Regulations is funded by central government. Under the current arrangements, the funding is included in the global sum for GP contracts. Payments made under the GP contracts include the costs of indemnity for services provided by GPs under those contracts. As part of the arrangements to establish the Scheme, the direct responsibility and risk associated with funding the costs of GP clinical negligence for these activities will transfer from individual GPs and GP practices to central government.

13. Regulating small business

- 13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

- 14.1 The Regulations establish the Scheme which is intended to provide more stable and affordable indemnity provision for general practice which will reduce workforce, patient and other risks to the NHS in England. The survey on indemnity in general practice conducted in 2018 for the Department by Ipsos Mori provides a baseline against which the Department can review the extent to which some of these objectives are achieved.⁴ The Department will also monitor and review the impact of the Scheme through existing networks with key stakeholders such as GP representatives.
- 14.2 NHS Resolution⁵ will exercise the Secretary of State's administration functions in respect of the Scheme and will be tasked with monitoring and keeping under review the on-going operation of the Scheme. NHS Resolution will report to the Secretary of State on the implementation, costs and progress of the Scheme.

15. Contact

- 15.1 Rachel Markey/Sean Palmer at the Department of Health and Social Care, (telephone: 0207 210 4358 / 0207 210 5127 or email: Markey_Palmer_Jobshare@dhsc.gov.uk) can be contacted with any queries regarding the instrument.
- 15.2 Stephen Rippon, Deputy Director for Resolution and Maternity at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Steve Brine MP, Parliamentary Under-Secretary of State (Public Health and Primary Care) at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.

⁴ https://www.ipsos.com/sites/default/files/ct/publication/documents/2019-01/18-009474-01_dhsc_gp_indemnity_research_2018_v2_public.pdf

⁵ NHS Resolution is the National Health Service Litigation Authority, a Special Health Authority, established by an order (S.I. 1995/2800) made under what is now section 28 of the National Health Service Act 2006.