EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (EXISTING LIABILITIES SCHEME FOR GENERAL PRACTICE) REGULATIONS 2020

2020 No. 296

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 the Existing Liabilities Scheme for General Practice ("ELSGP"), which is a state indemnity scheme that is to be administered by the Secretary of State for Health and Social Care. The ELSGP will provide indemnity cover for the tortious liabilities of general practitioners and others working in general practice (collectively referred to as "GPs") that arise in connection with NHS general practice activities carried out before 1st April 2019 ("existing liabilities"). Existing liabilities within scope of the ELSGP are those arising from the activities of GPs who are, or were, members of a medical defence organisation ("MDO") with which the Secretary of State has entered into contractual arrangements in relation to the ELSGP.

3. Matters of special interest to Parliament

Matters of special 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 existing liabilities arising in connection with services provided, or activities carried out, for the purposes of the NHS in England by GPs. This includes services delivered outside of England by a GP practice in England (for example, diagnosis, care or treatment that takes place in Wales in respect of a cross-border patient).

5. European Convention on Human Rights

5.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 This instrument is being made to establish the ELSGP in order to further the Department's policy of securing more stable, effective and affordable indemnity for GPs, in respect of liabilities incurred when providing services as part of the NHS in England.

6.2 The ELSGP is the second scheme to be established by regulations under section 71(1) of the National Health Service Act 2006 in relation to state indemnity for general practice activities carried out for the purposes of the NHS in England. The Clinical Negligence Scheme for General Practice ("CNSGP") was established on 1st April 2019 by the National Health Service (Clinical Negligence Scheme for General Practice) Regulations 2019 (S.I. 2019/3341) and covers NHS clinical negligence liabilities arising from general practice activities in England in relation to incidents that occur on or after 1st April 2019.

7. Policy background

What is being done and why?

Policy objectives and rationale

7.1 The policy objective underpinning both the ELSGP and the CNSGP is to introduce a more stable and affordable system for indemnifying general practice. Both offer value for money for taxpayers and are in the interests of GPs and NHS patients.

7.2 Whilst connected in terms of the policy intention, the CNSGP and ELSGP are separate schemes. The CNSGP is comprehensive in its cover of all NHS general practice liabilities arising from activities carried out from 1st April 2019. The ELSGP relates to liabilities arising from incidents that occurred before this date, but only provides cover to GPs in respect of such incidents where the GPs are members or former members of a medical defence organisation ("MDO") that has made a contractual agreement with the Department for such cover to be provided under the ELSGP.

7.3 All GPs and healthcare professionals are required, under various statutory provisions, to have appropriate indemnity or insurance arrangements in place before they are able, lawfully, to practise. Prior to April 2019, before the CNSGP was introduced, GPs and other primary care healthcare professionals largely purchased such cover annually from MDOs. MDOs are mutual, not-for-profit organisations which provide indemnity, on a discretionary basis, to healthcare professionals practising in England. The cover purchased by GPs from the MDOs was, traditionally, an occurrence-based product which provided ongoing cover for incidents that had occurred whilst a GP was a member of the MDO (i.e. even after the GP had retired, died or for any other reason was no longer a member of the MDO in question).

7.4 MDOs no longer provide indemnity for liabilities covered under the CNSGP but continue to offer products to general practice staff for matters not covered by the CNSGP, including indemnity relating to privately-funded healthcare and medico-legal services (for example, advice and assistance with regulatory matters and inquests).

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[1] Explanatory Memorandum for the National Health Service (Clinical Negligence Scheme for General Practice) Regulations 2019 - http://www.legislation.gov.uk/uksi/2019/334/pdfs/uksiem_20190334_en.pdf

7.5 Healthcare professionals who turned to MDOs for indemnity provision paid an annual, risk-based, subscription for membership of an MDO. The subscription payment factored in provision of indemnity for any claims made for existing liabilities covered by the MDOs' occurrence-based indemnity products.

7.6 The indemnity cover provided by MDOs is not subject to the regulatory requirements governing the provision of financial services and is on a discretionary basis.

7.7 Some indemnity cover for NHS clinical negligence liabilities of GPs was also provided by the commercial insurance industry under a contract of insurance (i.e. not on a discretionary basis) and, therefore, regulated under the financial services legislation that governs the provision of insurance products.

7.8 In October 2017, the Secretary of State publicly announced [2] that the Department was planning to develop a state scheme for general practice in England. One of the reasons for this was that MDO subscriptions for GP indemnity had been increasing by up to 10% a year for the previous six years. GPs reported that rising indemnity subscriptions had an impact on the sessions they were working, raising concerns about the impact on patient access to NHS primary care services[3].

7.9 The Secretary of State's announcement referred also to state indemnity for the existing liabilities of GPs, but made clear that this would be subject to satisfactory negotiation with the MDOs. The Government has engaged in commercial discussions with MDOs on the terms on which Government is willing to provide indemnity for the existing liabilities of general practice in England.

7.10 Separately from the work undertaken in developing an effective state indemnity scheme for general practice, the Department is reviewing policy on indemnity cover for healthcare professionals who continue to purchase their own indemnity cover because they are not covered by existing or proposed state indemnity schemes. A public consultation[4] was carried out between 6th December 2018 and 28th February 2019.

The Existing Liabilities Scheme for General Practice

7.11 As mentioned above, the Regulations establish a scheme to be known as the Existing Liabilities Scheme for General Practice (the ELSGP). The Regulations come into force on 6th April 2020, which is the date on which the ELSGP will be established.

7.12 The ELSGP will provide indemnity cover for the existing liabilities of GPs arising from the pre-April 2019 acts and omissions of members, or former members, of an MDO that has entered into contractual arrangements with the Secretary of State. The date from which the ELSGP will apply to those existing liabilities is 1st April 2021 but the Secretary of State has the power to determine an earlier date in relation to the liabilities arising from activities within scope of any of the MDO contractual arrangements.

7.13 As with the CNSGP, there are no membership or registration requirements under the ELSGP and no payments required from GPs who will benefit from the indemnity provided under it.

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[2] https://www.gov.uk/government/news/gp-indemnity-development-of-state-backed-scheme-for-england

[3] (NHS England and the Department of Health (2016) *GP Indemnity Review*, https://www.england.nhs.uk/wp-content/uploads/2016/07/gp-indemnity-rev-summary.pdf)

[4] https://www.gov.uk/government/consultations/appropriate-clinical-negligence-cover

Scope

7.14 The ELSGP will cover existing liabilities arising from the activities of GPs that are within scope of the MDO contractual arrangements referred to above. This includes liabilities arising from the acts and omissions of locums, trainees, dispensing doctors, nurses and clinical pharmacists. The activities covered under the ELSGP are the same type of activities as covered under the CNSGP. The main activity is the provision (or the making of arrangements for the provision) of primary medical services under contractual arrangements made under Part 4 of the National Health Service Act 2006.

7.15 Like the CNSGP, the ELSGP will also cover liabilities arising from the provision by general practice of other types of 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) or NHS services commissioned directly from GPs by clinical commissioning groups or NHS trusts, such as 'step-down' care to assist hospital patients to return home. The overall intention of the CNSGP and ELSGP is to provide state indemnity that covers GPs for all NHS activities they carry out for the NHS in England as part of the provision of services by general practice.

Exclusions

7.16 The ELSGP will not cover existing liabilities of GPs who are not members or former members of an MDO with which a contractual arrangement on the ELSGP has been agreed with Secretary of State.

7.17 The ELSGP will not cover liabilities relating to any activity that was not connected to the provision, by general practice, of NHS services. It does not cover existing 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 as part of the NHS. As the ELSGP only applies to the activities of GPs working in a general practice setting, it will not cover any NHS primary care services provided by health professionals who are not providing NHS services in a general practice setting, for example, dentists, optometrists or community pharmacists.

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 ELSGP was not undertaken. Instead, throughout the policy development for both the CNSGP and the ELSGP, the Department engaged, on an ongoing basis, with key stakeholders affected by the proposed changes arising from the implementation of a state scheme, including 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.[5] 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 policy for the schemes.

10.2 As part of the engagement process with key stakeholders, MDOs and GP representative bodies were given the opportunity to comment on a draft of the Regulations.

10.3 The Regulations apply only in relation to liabilities incurred in respect of services provided as part of the NHS in England. As with the CNSGP, we will work with the Devolved Administrations to monitor any consequential impact in Wales, Northern Ireland and Scotland. The Welsh Government has established a similar scheme to CNSGP and is in the process of establishing a similar scheme to ELSGP, in each case for general practice in Wales.

11. Guidance

11.1 Guidance on the ELSGP will be published in advance of 6th April 2020.

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, would be likely to prejudice commercial interests.

12.2 The Regulations have an impact on the business of the MDOs that have agreed contractual arrangements relating to the ELSGP with the Secretary of State.

12.3 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 liabilities arising from the NHS activities covered by these Regulations has previously been funded by 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 These Regulations establish the ELSGP. The establishment of the CNSGP and the ELSGP are significant milestones in meeting the Department's key objective of securing more stable, effective and affordable indemnity provision for general practice in England.

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

14.2 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 the objective is achieved.[6]

14.3 NHS Resolution[7] will exercise the Secretary of State's administration functions in respect of the ELSGP and will be tasked with monitoring and keeping under review the on-going operation of the ELSGP. NHS Resolution will report to the Secretary of State on the implementation, costs and progress of the ELSGP.

15. Contact

15.1 Sarah Richardson at the Department of Health and Social Care, (telephone: 0113 254 6696 or email: Sarah.Richardson@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 Nadine Dorries, Parliamentary Under Secretary of State for Mental Health, Suicide Prevention and Patient Safety at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.

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

[7] 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.