EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CROSS-BORDER HEALTHCARE) (AMENDMENT) REGULATIONS 2015

2015 No. 139

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations implement an outstanding measure of the Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State ("the implementing Directive") in relation to England and Wales. The provision (Article 4 of the implementing Directive) requires National Contact Points, the establishment of which is a requirement of the parent Directive, Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, to inform patients about the elements to be included in cross-border prescriptions. This refers to specific criteria that must be included on a prescription form if it is to be dispensed in another EU Member State.

2.3 This requirement will be transposed in relation to Scotland by the National Health Service (Cross Border Health Care) (Scotland) (Amendment) Regulations 2015 and in relation to Northern Ireland by The Health Services (Cross-Border Health Care) (Amendment) Regulations (Northern Ireland) 2015. The implementing Directive also applies to Gibraltar, where this measure has already been transposed.

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

3.1 None.

4. Legislative Context

4.1 These Regulations amend the National Health Service (Cross-Border Healthcare) Regulations 2013 and transpose the requirement at Article 4 of the implementing Directive requiring National Contact Points, referred to in Article 6 of the parent Directive, to inform patients about the criteria that must be included on a prescription form to be dispensed in another EU Member State. The Regulations come into force on 27 March 2015.

4.2 The National Health Service (Cross-Border Healthcare) Regulations 2013 transposed the requirements of Directive 2011/24/EU, apart from two measures:

- Article 4(2)(d) requiring all healthcare professionals to have indemnity cover, transposed by The Health Care and Associated Professions (Indemnity Arrangements) Order 2014;
- Article 11 on the recognition of prescriptions issued in another Member State – this concerns requirements to ensure prescriptions

are recognised and dispensed in a different Member State to the one issuing the prescription. The implementing Directive (Article 3 and associated Annex) also set down a list of elements to be included in cross-border prescriptions to facilitate their recognition. Article 11 of Directive 2011/24 and Article 3 of the implementing Directive were transposed by the Human Medicines (Amendment) Regulations 2014.

Scrutiny history

4.3 The implementing Directive provides greater clarity on the requirements of Article 11 of the parent Directive, Directive 2011/24/EU, which was subject to Parliamentary scrutiny. That scrutiny history is set out below.

4.4 The European Commission's Consultation regarding Community action on health services and the subsequent proposal for the Directive was considered by the Lords Scrutiny Committee. The then Minister, Rosie Winterton's letter of 26 October 2006 enclosed an Explanatory Memorandum of 27 October 2006 which was considered by the European Scrutiny Committee on 7 November 2006. The Committee responded to the Minister's offer to address the Committee and recommended a debate in European Standing Committee C, which was held on 16 January 2007 in the House of Commons. The proposal subsequently cleared scrutiny on 30th January 2007.

4.5 The House of Lords Select Committee on the European Union considered the same Minister's letter and Explanatory Memorandum at the meeting of their EU Sub-Committee G (Social Policy and Consumer Affairs) on 30 November 2006. The Minister visited the Committee to discuss the proposal on 25 January 2007. The Committee subsequently lifted scrutiny on 8 February 2007.

4.6 Scrutiny on the draft Directive published on 8 July 2008 included debates with the House of Commons Committee on 21 October 2008 and with the House of Lords Committee on 30 October 2008. Scrutiny was cleared in the House of Commons following the debate on 21 October 2010 and by the House of Lords on 2 July 2009.

4.7 Ministerial letters were then submitted to both Commons' and Lords' scrutiny committees on 31 January 2011 in order to update the committees on the cross border Directive proposal and to take account of the common position of the Council on first reading. The Directive cleared scrutiny in the Commons on 9 February 2011 and in the Lords on 3 March 2011 (having already granted a waiver giving the Government the go ahead to vote on the final text of the Directive on 28 February 2011).

5. Territorial Extent and Application

5.1 This instrument applies to England and Wales.

6. European Convention on Human Rights

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

7. Policy background

What is being done and why

7.1 Regulation (EC) No. 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and self-employed persons and to members of their families moving within the Community, which was replaced by revised provisions in Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems ("Regulation 883/2004") with effect from May 2010, already provide for reciprocal healthcare cover to EEA citizens.

7.2 However, over the past two decades, there have been more than a dozen high profile legal cases in which Member States' interpretation of the rules in respect of obtaining healthcare across borders has been questioned and on which the Court of Justice of the European Union (CJEU) has been asked to make a determination.

7.3 With so many ad hoc judgements being made in the courts, based on health systems which are very different in organisation and funding, the development of an EU-wide Directive, Directive 2011/24/EU, was seen as necessary to clarify the law and the rights of citizens across the EU.

7.4 The rationale underpinning the parent Directive is that it should be as easy as possible for patients to obtain a healthcare service in another Member State and (provided the equivalent treatment would have been made available to the patient under their home system) seek reimbursement of the cost. It sets out the arrangements that a Member State must provide to allow its own citizens to access their rights to obtain and seek reimbursement for the cost of cross-border healthcare and provides clarity on the information they are required to provide to citizens of other states considering coming to their country.

7.5 In order to help facilitate this, the Directive required the establishment of National Contact Points (NCPs). NCPs are national bodies charged with providing information, in appropriate formats, to prospective cross-border patients and facilitating the exchange of information with NCPs in other Member States. The NCP for England sits within NHS England, while that for Wales is located in the Welsh Ambulance Services NHS Trust.

7.6 One of the requirements of NCPs, as set out at Article 4 of the implementing Directive, is to make clear to patients the criteria to be included on cross-border prescriptions. It is this requirement to provide information about the criteria to be included which is being implemented by this instrument. The substantive mutual recognition requirement as to what has to be included in a cross-border prescription was also set out in the implementing Directive and implemented by the Human Medicines (Amendment) Regulations 2014.

7.7 The NCPs' other requirements are implemented in England and Wales by the National Health Service (Cross-Border Healthcare) Regulations 2013.

7.8 The parent and implementing Directives both had an implementation deadline of 25 October 2013.

8. Consultation outcome

8.1 The Government undertook an 8-week public consultation - from 28 March to 24 May 2013 - as part of its on-going work to transpose Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. In addition, a consultation event was held on 2 May 2013 attended by a variety of stakeholders. This allowed the Department of Health to set out what the Directive means for patients and the NHS and to seek views from stakeholders on the proposed implementation approach. Scotland, Wales and Northern Ireland carried out their own consultations. The consultation package for England may be found at the following link: https://www.gov.uk/government/consultations/eu-directive-on-patients-rights-to-healthcare-in-other-european-countries

8.2 A total of 31 responses to the consultation were received. These revealed that there was no substantial disagreement with Government's overall approach to implementing the Directive and the majority of respondents expressed positive views on the scope and effect of this new European health legislation.

8.3 Wales undertook its own consultation exercise between 21 December 2012 and 15 March 2013. Out of the 22 responses received there were a number of comments made providing some common themes for consideration, particularly around the key areas of entitlements, prior authorisation and the national contact point. Responses broadly supported the scope of what was being planned. The Welsh Government's formal response to this consultation can be found through the following link: http://wales.gov.uk/consultations/healthsocialcare/patient/?status=closed&lang=en

8.4 No additional consultation has been carried out in relation to these specific regulations due to their very narrow scope.

9. Guidance

9.1 Guidance on the requirements of the parent Directive as a whole has been made available to the NHS through GOV.UK (https://www.gov.uk/government/organisations/department-of-health).

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 The impact on the public sector is negligible.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The European Commission is required to report on the operation of the parent Directive (Directive 2011/24/EU) by 25 October 2015 and then every three years thereafter. The Department of Health and NHS England are jointly monitoring, on an ongoing basis, the operation of the Directive and the domestic implementing legislation, including how these work in practice for patients and for the health service as a whole.

12.2 The National Health Service (Cross-Border Healthcare) Regulations 2013 will be reviewed formally at five year intervals after they come into force. This is a Government requirement. The first report will be published by 25 October 2018.

13. Contact

13.1 Rob Dickman at the Department of Health can answer any queries regarding the instrument.
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