

**EXPLANATORY MEMORANDUM TO**  
**THE HEALTH SERVICES (CROSS-BORDER HEALTH CARE)**  
**(AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2015**

**2015 No. 130**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Department of Health, Social Services and Public Safety, “the Department” to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2 The Statutory Rule is made under section 2(2) of the European Communities Act 1972 and is subject to negative resolution procedure.

**2. Purpose**

- 2.1 These Regulations implement an outstanding measure of the EU 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 Northern Ireland. 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 EEA country.
- 2.2 This requirement will be transposed in relation to England and Wales by The National Health Service (Cross-Border Healthcare) (Amendment) Regulations 2015 and in relation to Scotland by The National Health Service (Cross Border Healthcare) (Scotland) (Amendment) Regulations 2015. The implementing Directive also applies to Gibraltar, where this measure has already been transposed.

**3. Background**

- 3.1 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 provides for reciprocal healthcare cover to EEA citizens.

- 3.2 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.
- 3.3 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.
- 3.4 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.
- 3.5 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 Northern Ireland sits within the Health and Social Care Board.
- 3.6 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 these regulations. 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 UK-wide legislation - the Human Medicines (Amendment) Regulations 2014.
- 3.7 The NCPs' other requirements are implemented in Northern Ireland by the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013.
- 3.8 The parent and implementing Directives both had an implementation deadline of 25 October 2013.

#### **4. Consultation**

- 4.1 The Department undertook an 8 week consultation from 22 July to 13 September 2013 as part of its on-going work to transpose the parent Directive (Directive 2011/24/EU) on the application of patients' rights in cross-border health care. A total of 13 responses to the consultation were received. These revealed that there was no substantial disagreement with the Department's overall approach to implementing the Directive and in general recognised the Department's responsibility for ensuring that our legislation is consistent with European law under the Directive. England, Wales and Scotland carried out their own consultations.
- 4.2 Similar to the rest of the UK, no additional consultation has been carried out in relation to these specific regulations due to their very narrow scope

#### **5. Equality Impact**

- 5.1 In line with the commitments in its Equality scheme, the Department conducted a Preliminary Equality Impact Assessment (PEQIA) on the policy proposal being introduced by these regulations. The PEQIA did not identify any potential for adverse impact on any of the nine section 75 categories.

#### **6. Regulatory Impact**

- 6.1 An assessment was not considered necessary as these Regulations do not apply to small businesses and have no impact on the charitable sector or voluntary bodies.

#### **7. Financial implications**

- 7.1 There will be no financial implications flowing from these Regulations.

#### **8. Legislative Context**

- 8.1 These Regulations amend the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 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 EEA country. The Regulations come into force on 27th March 2015.
- 8.2 The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 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 in the UK by the Human Medicines (Amendment) Regulations 2014. The implementing Directive provides greater clarity on the requirements of Article 11 of the parent Directive.

## **9. Section 24 of the Northern Ireland Act 1998**

- 9.1 Considered compliant with Section 24 of the Northern Ireland Act 1998.

## **10. EU Implications**

- 10.1 These Regulations implement in Northern Ireland an outstanding measure of the EU 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.

## **11. Parity Measures**

- 11.1 The regulations bring Northern Ireland into line with the rest of the UK in relation to our obligations under the implementing Directive.

## **12. Additional Information**

- 11.1 None