#### EXPLANATORY MEMORANDUM TO

# THE HEALTH SERVICES (CROSS-BORDER HEALTH CARE) REGULATIONS (NORTHERN IRELAND) 2013

#### S.R. 2013 No. 299

#### 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 the negative resolution procedure.

## 2. Purpose

- 2.1. These Regulations implement the majority of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare ("the Directive") in relation to Northern Ireland.
- 2.2. The Directive will be transposed in relation to England and Wales by the National Health Service (Cross Border Healthcare) Regulations 2013 and in Scotland by the National Health Service (Cross Border Healthcare) (Scotland) Regulations 2013. The Directive also applies to Gibraltar, where separate arrangements are being made to transpose it.

### 3. Background

- 3.1. The majority of EU citizens receive health care in the member State where they live, via the health system through which they are covered or insured. However, in some instances, it may benefit the patient to obtain health care in another European country for example, where there may be better expertise available, lower costs, better availability of certain highly specialised treatments or where waiting times are shorter.
- 3.2. 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 health care cover to EEA citizens. In summary, Regulation 883/2004 provides for the following:
  - (a) Health care that becomes necessary during a visit to another member State (for example on holiday or on business) is to be provided by the member State in which the person is temporarily staying on the same

- basis as health care is provided to residents (via the European Health Insurance Card);
- (b) Health care for individuals in receipt of a pension paid under the legislation of the member State that is the competent member State under Regulation 883/2004 and who reside in another member State and health care for members of the pensioner's family. For example this provision enables UK state pensioners who retire to live in Spain to access the Spanish healthcare system;
- (c) Health care provision for people who move to work and live in another member State.
- 3.3. While these reciprocal arrangements have existed for many years, current generations of Europeans, accustomed to crossing borders with ease and being able to purchase goods and services from any part of the EU, are proving less willing to accept constraints on how and where they obtain their health care. This is often due to perceived advantages relating to quality, favourable cost, waiting times, the availability of different treatments or where citizens have close cultural or familial links in another country.
- 3.4. 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 health care across borders has been questioned and on which the Court of Justice of the European Union (CJEU) has been asked to make a determination. The development of this case law based on individual cases (including Case C-372/04 The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health ([2006] ECR I-4325), "the Watts judgment"), was inevitably piecemeal and could not provide a coherent overall approach to the rules surrounding patient mobility in Europe.
- 3.5. 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 was seen as necessary to clarify the law and the rights of citizens across the EU. This new EU legislation reflects existing rights under the Treaties, the principles confirmed by established CJEU case law and applies best practice in providing access to these rights. Its main objectives are to:
  - o clarify the rules and procedures for reimbursement where a patient obtains a health care service in another member State and seeks reimbursement of the costs of their expenditure;

- o facilitate the right to obtain services and support patient choice;
- o provide EU citizens with better information on their rights;
- o ensure that cross-border health care is safe and of high-quality; and
- o promote cooperation between member States.
- 3.6 The rationale underpinning the Directive is that it should be as easy as possible for patients to obtain a health care service (provided the equivalent treatment would have been made available to the patient under their home system) in another member State and 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 health care and provides clarity on the information they are required to provide to citizens of other States considering coming to their country.
- 3.7 In order to help facilitate this, the Directive requires the establishment of National Contact Points (NCPs). NCPs will be 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 will sit within the Health and Social Care Board.
- 3.8 Importantly, the 'home' State retains responsibility for deciding what health care is made available to its citizens and thus what costs are reimbursable where a patient obtains health care services in another member State.

  Therefore, the Directive is not a way for a patient to obtain reimbursement for health care treatments that would not be made available to the patient under their home health service. However, this means that to exercise their rights patients need to be able to obtain information about health care that would be made available to them within the health service. Reimbursement levels are not required to be more than the cost of the equivalent treatment that would have been made available to the patient within the health service.
- 3.9 Following the Watts judgment the Health and Personal Social Services (Northern Ireland) Order 1972 was amended to provide for reimbursement of the cost of expenditure on a health care service obtained in another EEA State incurred on or after 10 May 2012. These Regulations to transpose the Directive build on the existing domestic legislation.
- 3.10 The Directive includes requirements on member States for health care that is provided on its territory to patients from other member States seeking planned treatment ("visiting patients"). Recital 21 to the Directive recognises that

nothing in the Directive should oblige health care providers to accept patients from another member State seeking planned treatment or to prioritise such patients. However, if accepted for treatment, the Directive requires that the principle of non-discrimination applies. Article 4(3) of the Directive provides that where justified by overriding reasons of general interest a member State may adopt necessary and proportionate measures on access to treatment to ensure it can fulfil its fundamental responsibility to ensure sufficient and permanent access to health care within its territory.

- 3.11 The Directive requires member States to ensure that a visiting patient can obtain specified information from the NCP. Article 4(4) provides that the same scale of fees should apply to visiting patients as domestic patients however where there is no comparable charge, such as in the health service, it provides that the price is to be calculated according to objective non-discriminatory criteria. Regulation 11 provides that where a visiting patient obtains a chargeable health service treatment under the Directive the amount should not exceed the amount that would have been assessed as the cost if that service had been provided to a health service patient.
- 3.12 Article 7(2) of the Directive concerns certain provisions in Regulation 883/2004 for state pensioners, their family members and the family members of frontier workers (workers who work in one member State and reside in another member State). Where such a person is staying temporarily in the member State that is the competent Member State under Regulation 883/2004 the member States listed in Annex IV to the Regulation provide that person with healthcare which is not limited to healthcare that is necessary during the visit. The United Kingdom is not listed in Annex IV to Regulation 883/2004.
- 3.13 The United Kingdom is listed in Annex III to Regulation 883/2004. Member States listed in Annex III provide health care that it is necessary to provide during a visit. For these member States (including the UK) the effect of Article 7(2)(b) of the Directive is to require them to provide to their state pensioners, their family members and the family members of frontier workers with health care that is not limited to care that is necessary during a visit, but excluding health care that is subject to prior authorisation. For example, during a visit to the UK a UK state pensioner resident in Spain may obtain health care that is not limited to health care that is required during their visit but excluding healthcare that is subject to prior authorisation. Article 7(2)(b) is implemented by regulation 12.
- 3.14 Where the Directive imposes a requirement which is already adequately met by existing domestic measures this is indicated in the Transposition Note.

3.15 The Directive came into effect on 25 October 2013 and the Health Services (Cross-Border Health Care) Regulations 2013 will come into force on the 27 December 2013. Directions under the Health and Social Care (Reform) Act (Northern Ireland) 2009 will be made by the Department which will direct the HSCB on the detail of certain administrative requirements.

#### 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 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.

# 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 proposals being introduced. The PEQIA did not identify any potential for adverse impact on any of the nine section 75 categories.

#### 6. Regulatory Impact

An assessment was not considered necessary as these Regulations do not apply to small businesses and the impact on the charitable sector is negligible.

## 7. Financial Implications

7.1 The Directive codifies many years of case law on patient mobility in Europe, established over the last decade or so. Its purpose is not to foster or promote cross-border health care but to facilitate the exercise of patient choice to access health care services in another member State. Any additional financial implications flowing from these regulations will be minimal.

### 8. Legislative context

- 8.1 Following the Watts judgement, the Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012 (S.R. 2012 No.167) amended the Health and Personal Social Services (Northern Ireland) Order 1972, "the Order of 1972", (S.I. 1972/1265 (N.I. 14), by inserting Articles 14B and 14C into that Order of 1972. These Articles provide for the reimbursement of the cost of a Health care service which a patient chooses to obtain in another EEA State. They also provide for prior authorisation. The Department has directed the Health and Social Care Board to exercise its functions under Article 14B and 14C of the Order of 1972 via the Functions of Health and Social Care Boards (No. 1)(Amendment) Direction (NI) 2012, "the 2012 Directions".
- 8.2 These Regulations amend the Order of 1972 to insert new Articles 14D and 14E to provide for reimbursement in accordance with the requirements of the Directive. The provisions in Articles 14D and 14E apply to expenditure incurred on or after 25 October 2013. Article 14D sets out the duty to reimburse a person the cost of expenditure; the services where prior authorisation is required; limits reimbursement to the equivalent Health care cost and provides for the deduction of health care charges. Article 14E provides for applications for prior authorisation and specifies the four cases where authorisation may be refused. The Department will be making Directions to provide for the Health and Social Care Board to determine applications under Articles 14D and 14E of the Order of 1972.
  - 8.3 The Regulations also transpose the requirements in relation to national contact points and make provision for charges for healthcare provided by the Department to residents of other member States in accordance with the 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 transpose the Directive with the exception of Article 11 (recognition of prescriptions issued in another member State) and Article 4(2)(d) (requirement for liability insurance or similar arrangement) which will be transposed by separate statutory rules.

# 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 Directive.

# 12. Additional Information

12.1 None