EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CROSS-BORDER HEALTHCARE) REGULATIONS 2013

2013 No. 2269

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 the majority of the 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 England and Wales.

2.2 The Directive will be transposed in relation to Scotland by the National Health Service (Cross Border Healthcare) (Scotland) Regulations 2013 and in relation to Northern Ireland by The Health Services (Cross-Border Healthcare) Regulations (Northern Ireland) 2013. The Directive also applies to Gibraltar, where separate arrangements are being made to transpose it.

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

3.1 None

4. Legislative Context

4.1 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 instruments. A transposition note is at Annex A to this Memorandum. The Regulations come in to force on the transposition deadline of 25 October 2013.

4.2 Following the judgement in 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") the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 (S.I. 2010/915) amended the National Health Service Act 2006 (c.41) and of the National Health Service (Wales) Act 2006 (c.42) to insert sections 6A and 6B into both Acts. These sections provide for the reimbursement of the cost of a healthcare service which a patient chooses to obtain in another EEA State. Part 2 of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013 (S.I. 2013/261) provides for the National Health Service Commissioning Board (known as "NHS England") to exercise the functions of the Secretary of State in determining applications under section 6A and 6B of the National Health Service Act 2006. In Wales, the Welsh Ministers have directed Local Health Boards to exercise their functions under section 6A and 6B of the National Health Service (Wales) Act 2006 in the National Health Service (Reimbursement of the Cost of EEA Treatment) (Wales) Directions 2010 ("the 2010 Directions").

4.3 These Regulations amend the National Health Service Act 2006 and the National Health Service (Wales) Act 2006 to insert new sections 6BA and 6BB to provide for reimbursement in accordance with the requirements of the Directive. The provisions in sections 6BA and 6BB apply to expenditure incurred on or after 25 October 2013. Section 6BA sets out the duty to reimburse a person the cost of expenditure; the services where prior authorisation is required; limits reimbursement to the equivalent NHS cost and provides for the deduction of NHS charges. Section 6BB provides for applications for prior authorisation and specifies the four cases where authorisation may be refused.

4.4 The Regulations also amend Part 2 of the National Health Service and Public Health (Functions and Miscellaneous Provisions) Regulations 2013 to provide for the National Health Service Commissioning Board to determine applications under sections 6BA and 6BB. Welsh Ministers will be amending the 2010 Directions to provide for Local Health Boards to determine applications under sections 6BA and 6BB of the National Health Service (Wales) Act 2006.

4.5 The Regulations also transpose the requirements in relation to national contact points and makes provision for NHS charges for healthcare provided by the NHS to residents of other member States in accordance with the Directive.

Scrutiny history

4.6 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.

4.7 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.

4.8 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.

4.9 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

Anna Soubry MP (Parliamentary Under-Secretary of State at the Department of Health and the Minister responsible for this Directive) has made the following statement regarding Human Rights:

In my view the provisions of the National Health Service (Cross-Border Healthcare) Regulations 2013 are compatible with the Convention rights.

7. Policy background

What is being done and why

7.1 The majority of EU citizens receive healthcare 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 healthcare 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.

7.2 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 healthcare cover to EEA citizens. In summary, Regulation 883/2004 provides for the following:

(a) Healthcare that becomes necessary during a visit to another member State (for example on holiday or on business) to be provided by the Member State in which the person is temporarily staying on the same basis as healthcare is provided to residents (via the European Health Insurance Card);
(b) Healthcare 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 healthcare 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) Healthcare provision for people who move to work and live in another member State.
(d) In addition a patient may apply for authorisation to travel specifically to receive planned healthcare service in another Member State. These

arrangements are publicised on the NHS Choices website at the following link: http://www.nhs.uk/NHSEngland/Healthcareabroad/plannedtreatment/Pages/Introduction.aspx

7.3 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 healthcare. 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.

7.4 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 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. The development of this case law based on individual cases (including the Watts judgment in 2006), was inevitably piecemeal and could not provide a coherent overall approach to the rules surrounding patient mobility in Europe.

7.5 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:

- Clarify the rules and procedures for reimbursement where a patient obtains a healthcare service in another Member State and seeks reimbursement of the costs of their expenditure;
- Facilitate right to obtain services and support patient choice;
- Provide EU citizens with better information on their rights;
- Ensure that cross-border healthcare is safe and of high-quality;
- Promote cooperation between Member States.

7.6 The rationale underpinning the 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.

7.7 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 England will sit within the National Health

Service Commissioning Board (known as 'NHS England'), while that for Wales will be located in the Welsh Ambulance Services NHS Trust.

7.8 Importantly, the 'home' state retains responsibility for deciding what healthcare is made available to its citizens and thus what costs are reimbursable where a patient obtains healthcare services in another Member State. Therefore, the Directive is not a way for a patient to obtain reimbursement for healthcare 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 healthcare that would be made available to them within the national health system. 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 national health system.

7.9 Following the Watts judgment legislation was introduced providing for reimbursement of the cost of expenditure on a healthcare service obtained in another EEA State incurred on or after 23 August 2010. These Regulations to transpose the Directive build on the existing domestic legislation.

7.10 The Directive includes requirements on member States for healthcare 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 healthcare 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 healthcare within its territory.

7.11 The Directive requires member States to ensure that a visiting patient can obtain specified information from the national contact point. 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 NHS) it provides that the price is to be calculated according to objective non-discriminatory criteria. Regulation 13 provides that where a visiting patient obtains a chargeable NHS service 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 NHS patient.

7.12 Article 7 (2) of the Directive concerns certain provisions in Regulation 883/2004 for state pensioners and the family members of frontier workers (workers who work in one member State and resides 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.

7.13 Member States (including the UK) listed in Annex III to the Regulation provide healthcare that it is necessary to provide during the 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 health care that is not limited to care that is necessary during a visit but excluding healthcare that is subject to prior authorisation. For example, during a visit to the UK a UK state pensioner resident in Spain may obtain NHS care that is not limited to healthcare that is required during their visit but excluding healthcare that is subject to prior authorisation. Article 7(2)(b) is implemented by regulation 14.

7.14 Where the Directive imposes a requirement which is already adequately met by existing domestic measures this is indicated in the Transposition Notes.

7.15 The Directive comes into effect on 25 October 2013 and the National Health Service (Cross-Border Healthcare) Regulations 2013 will come into force on the same date. Directions under the NHS Act will be made by the Secretary of State which will direct NHS England and local clinical commissioning groups on certain of the detailed administrative requirements. Similar arrangements are planned by the Welsh Government.

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. The Government's official response to the consultation is published alongside these Regulations.

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

9. Guidance

9.1 Guidance will be 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 estimated as minimal overall, being largely confined to centralisation of EU functions at NHS England. The Government is confident that the transposition of the Directive will not generate additional costs that will be unmanageable within the TDEL limits set at SR10 and SR13.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk. This received a 'green rating' from the Regulatory Policy Committee.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Commission are required to report on the operation of the Directive by 25 October 2015 and then every three years thereafter. The Department of Health and NHS England will jointly monitor, 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 Regulations 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

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