EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (REIMBURSEMENT OF THE COST OF EEA TREATMENT) REGULATIONS 2010

2010 No. 915

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 This instrument is made under powers conferred by section 2(2) of the European Communities Act 1972 in relation to the National Health Service and under sections7, 272(7) and 273(4) of the National Health Service Act 2006 (c.41.) It gives effect to judgments made by the European Court of Justice,("the ECJ") in particular 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"*).* Its purpose is to make provision for the reimbursement of the cost of a health care service where a patient chooses to obtain that service in another EEA State under the provisions of Article 56 of the Treaty on the Functioning of the European Union.

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

3.1 None

4. Legislative Context

4.1 The *Watts* judgment established that the freedom to provide and receive services under Article 56 applies to non insurance-based health systems such as the NHS and includes the right for a patient to seek reimbursement of the costs of such treatment from their home health system.

4.2 This instrument provides for transparency by setting out in legislation the duty to reimburse a person for the cost of expenditure, subject to certain conditions and limitations, the services for which prior authorisation must be obtained and when such authorisation must be granted.

5. Territorial Extent and Application

5.1 This instrument applies to England and Wales.

6. European Convention on Human Rights

The Minister of State for Public Health, Gillian Merron MP has made the following statement regarding Human Rights:

In my view, the provisions of the The National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 are compatible with the Convention rights.

7. Policy background

- ***What is being done and why***

7.1 The ECJ, in the *Watts* judgment, found that patients have rights under what is now Article 56 to receive medical services in another Member State and to be reimbursed the costs of those services by their home health system and that these rights apply equally to NHS patients. These, and other healthcare-related Treaty rights accorded to citizens as determined by the ECJ in its judgments, will in due course be codified and clarified within a European Directive, which is currently in the process of negotiation between Member States.

7.2 Under Article 56, restrictions on the fundamental freedom to provide services are prohibited unless the restriction is capable of objective justification such as the risk of seriously undermining the financial balance of a social security system; the objective of maintaining a balanced medical and hospital service open to all; or the objective of maintaining treatment capacity or medical competence. In order to be lawful the criteria must transparent, objective and non-discriminatory and easily accessible and known in advance.

7.3 The ECJ made clear that national systems may impose a requirement for patients to obtain approval from their local healthcare commissioners and that such a restriction can be justified. The Court has also ruled that prior authorisation should always be granted if their home health service cannot make the required service available to the patient "without undue delay". The ECJ identified certain factors that should be considered in assessing whether or not the service can be provided without undue delay. These factors are reflected in these Regulations.

7.4 The purpose of these Regulations is to provide certainty and transparency following the Watts judgment, in relation to arrangements for reimbursement of costs, the circumstances in which prior authorisation is required and when prior authorisation must be granted.

7.5 As the ECJ has made clear, in order for a system of prior authorisation to be justified it must be based on objective non-discriminatory criteria, which are known in advance and circumscribe the national authorities' discretion so that they are not used arbitrarily. The rules surrounding prior authorisation and reimbursement of costs must also be easily accessible and capable of ensuring that a request will be dealt with impartially within a reasonable time.

7.6 Accordingly, the reason for making provision for the exercising of reimbursement and prior authorisation mechanisms in these Regulations is to set out the arrangements including the restrictions and limitations on the right to reimbursement in legislation to make the arrangements transparent and easily accessible. Similar legislation is planned in the devolved assemblies in Scotland and Northern Ireland.

7.7 Directions under the NHS Act will be made by the Secretary of State which will direct Primary Care Trusts in England to exercise the functions of the Secretary of State in relation to reimbursement of costs under section 6A and prior authorisation under section 6B. Similar arrangements are planned by the Welsh Assembly Government.

7.8 The Regulations will be accompanied by guidance to the NHS.

Effect

7.9 The Regulations insert new sections 6A and 6B into the National Health Service Act 2006 (c.41.) and the National Health Service (Wales) Act 2006 (c.42.). The new section 6A in each Act places a duty on the Secretary of State and the Welsh Ministers respectively to reimburse the cost of services provided to a patient in another EEA State which are incurred on or after 23 August 2010 where the conditions set out in that section are met. The date of 23 August is intended to allow sufficient lead-in time for the NHS to ensure that the requisite systems are in place. Reimbursement may be limited to the amount that it would have cost the NHS to provide the service and may be subject to deduction of NHS charges that would have been payable for the same or equivalent service if it had been provided through the NHS. This section also sets out when prior authorisation is required. The new section 6B makes provision for applications for prior authorisation required under section 6A and when prior authorisation must be granted.

- ***Consolidation***

7.10 There is no consolidation of existing legislation planned at present.

8. Consultation outcome

8.1 Ministers agreed that, due to the technical nature of these measures and applicability to NHS processes, and because a full public consultation had already taken place on these issues, it was prudent to undertake a limited stakeholder engagement exercise with the NHS and associated bodies. This was conducted between 23 October and 11 December 2009. This process attracted a low level of interest and threw up few surprises. Respondents welcomed the clarity brought to this area by the proposed regulations and supported their introduction. A further full public consultation will take place on the provisions of the final Directive, when this is agreed at European level.

9. Guidance

9.1 Detailed guidance will be made available to the NHS through the Department of Health website (www.dh.gsi.gov.uk). A copy of this has been placed in the libraries of both Houses.

10. Impact

10.1 The impact on business, charities or voluntary bodies is estimated as minimal.

10.2 The impact on the public sector is estimated as minimal.

10.3 An Impact Assessment has not been prepared for these instruments. The Government has already consulted publicly on patient rights issues following publication of the draft Cross-border Healthcare Directive in 2008. A further full public consultation (including updated Impact Assessments) will take place on the provisions of the final Directive, when this is agreed at European level.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 This instrument aims to ensure that the NHS is complying with European case law. The Department will keep the effect of these regulations under review, pending the agreement of a wider and more comprehensive EU Directive on patient mobility currently being negotiated between EU Member States.

13. Contacts

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