EU CROSS-BORDER HEALTHCARE

Overview of Research Briefing

This research briefing outlines the main points of the proposed *Directive of the European Parliament and of the Council on the Application of Patient's Rights in Cross-Border Healthcare*, placing it in the context of existing arrangements. The briefing looks at the potential impact of the proposed Directive, both in the opinion of the EU Commission and more specifically for the UK in the context of the Department of Health's consultation on the matter. The briefing finishes with a brief look at both a sample of EU cross-border healthcare projects and the issue of cross-border healthcare pertaining to the border between Northern Ireland and the Republic of Ireland.

1. Context of the Proposed Directive

1.1 Existing Arrangements

Patients can currently access healthcare in another European Union (EU) Member State via several existing arrangements.

Firstly, the European Health Insurance Card (EHIC) allows access to emergency healthcare while in the EU and patients may have to pay for some of this healthcare depending on the arrangements in the host country[1].

Secondly, healthcare for groups of people who live and/or work in another EU Member State, such as pensioners and workers are covered by an EU-wide social security agreement known as Regulation 1408/71. This route also allows people with an NHS entitlement to go to another Member State for planned public sector treatment under the E112 scheme, for example, if the treatment cannot be provided without 'undue delay' in the home country[2].

Thirdly, in addition to the planned treatment outlined above using the E112 scheme, the EU Court of Justice judgements over the last decade have established that EU citizens should be able to access treatment in other EU states under Article 49 of the Treaty establishing the European Community, even for citizens accessing tax-funded systems like the NHS[3]. Article 49 prohibits restrictions on the freedom to obtain services within the EU and using this route may allow a patient to obtain

[1] European Health Insurance Card www.nhs.uk/EHIC/Pages/About.aspx
[2] Planned Treatment via E112 www.nhs.uk/Treatmentabroad/Pages/Plannedtreatment.aspx.
[3] Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health (Oct. 2008), www.dh.gov.uk/en.Consultations/closedconsultations/DH_089029

reimbursement of the cost of treatment in another EU country so long as it is treatment that could have been accessed at home. Reimbursement can only be sought for what the treatment would have cost in the NHS. Within the UK this option was introduced subsequent to the case of an NHS patient, Yvonne Watts, who went to France for a hip replacement to avoid a long waiting list in England. The Primary Care Trust refused to reimburse her costs and she then took her case to the courts, finally reaching the European Court of Justice (ECJ). This case was important for the NHS as it established that EU rules on patient mobility applied to the NHS[4].

It has been commented that the reason Europe came to regulate national healthcare has occurred not "*as an output of rational political decision-making, but rather as a 'side-effect' of how the European Court of Justice gradually conferred a 'supreme' status to the free movement provisions in the EU legal construct*". Since 1998, it has become "*irrevocably clear that the policy domain of healthcare is 'hardly an island beyond the reach of Community law*"[5].

It is believed that the proposed Directive will provide necessary legal clarity in many areas, however it is noted that it may also "*raise new problems that may need to be tested in the courts… The most controversial of these may be how member states apply the agreed values and principles…the proposals will probably lead to a wide ranging debate on the considerable cultural differences seen in European health systems*"[6].

1.2 Patient Mobility

To inform the preparation of the proposed Directive and to assess cross-border healthcare from the citizen's perspective, the *European Commission Directorate General for Health and Consumer Protection* polled citizens from all EU countries about their experiences and expectations concerning patient mobility. The poll was conducted mainly by telephone[7]. The main findings of the survey were as follows[8]:

- 70% of the EU citizens tended to believe that costs of healthcare treatment received elsewhere in the EU would be reimbursed by their health authority;
- 4% of EU citizens had received medical treatment in another Member State in the previous 12 months, most significantly in Luxembourg where it applied to one in five citizens;
- 54% of EU citizens were open to travelling to another EU Member State for medical treatment for the hypothesised reasons of lack of availability in home country, hope of better quality and faster access to treatment;
- The 42% not willing to travelling abroad were motivated by different reasons in the old and new Member States, including affordability problems and satisfaction with domestic services respectively.

2. Rationale and Key Provisions of the Proposed Directive

The proposed Directive has been described as part of a renewed social agenda package aimed at clarifying citizens' rights in line with the rulings of the European

[4] Cross-border healthcare, The NHS Confederation, www.nhsconfed.org/euunit/euunit-3874.cfm
[5] Martinsen, M.D. (2005), Towards an Internal Market with the European Court, *West European Politics*, 28 (5), 1035-1056
[6] McKee, M. (2008), Cross border health care in Europe, *BMJ*, 337: a610
[7] Due to low fixed telephone coverage in certain countries, for example, Poland and Hungary, 300 face to face interviews were also carried out.
[8] Cross-border services in the EU, Flash EB Series #210, Gallop Organisation, Hungary, June 2007, page 5, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/ebs_210_en.pdf

Court of Justice. This social agenda package also "*includes measures to improve access to jobs and fight discrimination and poverty*"[9].

Healthcare was excluded from a previous Directive, 2006/123/EC, on services in the internal market and the Council and the Parliament requested that the Commission address issues in relation to cross-border healthcare in a separate instrument. On that basis, and via a consultation process, the Commission developed the draft Directive on patients' rights in cross-border healthcare. In order to resolve the uncertainty that remains over how to apply the principles of the jurisprudence of the European Court of Justice rulings, confirming that the EU Treaty gives individual patients the right to seek healthcare in other Member States and be reimbursed at home, "*this proposal aims to clarify how patients can exercise their rights to cross-border healthcare, while at the same time providing legal certainty for Member States and health care providers*"[10].

The overall aim of the Directive, once adopted by the Council and the European Parliament, is to provide a clear framework for cross-border care and its key provisions include[11]:

- Clarifying how patients have the right to seek healthcare abroad and be reimbursed up to what they would have received at home with clarity being provided over how these rights can be exercised within certain limits and financial coverage that Member States can place on such healthcare;
- Outlining how Member States are responsible for the safety and quality of healthcare provided on their territory;
- Enhancing European cooperation on healthcare by supporting the development of European reference networks, bringing together on a voluntary basis specialised centres in different Member States;
- Minimising duplication of effort in the field of health technology assessment; and
- Strengthening activities in the field of e-health.

3. Details of the Proposed Directive

3.1 Structure of the Directive

The proposed Directive is structured around three main areas as follows[12]:

1. Common principles in all EU health systems – "*as agreed in June 2006 by the Council, setting out which Member State will be responsible for ensuring compliance with the common principles for healthcare and what those responsibilities include*…";
2. A specific framework for cross-border healthcare – "*the directive will make clear the entitlements of patients to have healthcare in another Member State, including the limits that Member States can place on such healthcare abroad,*

[9] EU plans cross-border healthcare, BBC News Channel, 2 July 2008, http://news.bbc.co.uk/1/hi/world/europe/7484198.stm
[10] Commission adopts proposal for directive on patients' rights in cross-border healthcare, Press Release, Brussels, 2 July 2008, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1080&format=HTML
[11] Commission adopts proposal for directive on patients' rights in cross-border healthcare, Press Release, Brussels, 2 July 2008, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1080&format=HTML
[12] A community framework on the application of patients' rights in cross-border healthcare, Communication from the Commission, Brussels 2.7.2008, COM(2008) 415 final, pages 3-4, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com2008415_en.pdf

and the level of financial coverage that is provided for cross-border healthcare, based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home"; and

3. European cooperation on healthcare – "*the Directive establishes a framework for European cooperation in areas such as, European reference networks, health technology assessment, data collection and quality and safety…".*

3.2 Chapter I of the Draft Directive – Aim and Scope

The overall aim is to ensure "*there is a clear framework for cross-border healthcare within the EU… the uncertainty about the application of rights to reimbursement for healthcare provided in other Member States is creating obstacles to the free movement of patients, and of health services more generally, in practice*"[13].

The scope of the proposed Directive is that it applies "*to all healthcare provision, regardless of how it is organised, delivered or financed"* as it is *"impossible to know in advance whether a given healthcare provided will supply healthcare to a patient coming from other Member States or to patients from its own Member State*"[14].

3.3 Chapter II of the Draft Directive – Responsibilities of the Authorities of the Member State of Treatment

This chapter provides clarity that it is the responsibility of the authorities in the Member State in which treatment is provided for ensuring that there is adherence to a minimum set of common principles on which patients and professionals from other Members States can rely. This implies a degree of harmonisation and to ensure that this "*remains proportionate, the principles in the directive take as a basis the Council conclusions on 'Common values and principles in the European Union Health Systems' of June 2006, and therefore should not require major adaptations of existing systems*"[15].

The first three common principles are to ensure "*that the fundamental elements for ensuring quality and safety of healthcare are in place*"[16], (i) clear definition by authorities of Member State of standards of quality and safety; (ii) transparency of applicable standards for both patients and professionals; and (iii) mechanisms to ensure the translation of the standards into practice (and monitoring of standards).

The remaining common principles are as follows[17]:

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[13] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 5.1, pg 9

[14] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 5.2, p 10

[15] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 6.1 p 11

[16] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 6.1, p 11

[17] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final,

- Member States have to provide access to the "*key medical, financial and practical information*" for patients for the healthcare they are seeking as to not do so would be an obstacle to free patient movement;
- Member States have to set up "*procedures and systems to be used in case of harm caused when healthcare is provided*";
- The Member State of treatment "*has to ensure that mechanisms for patients to seek redress and compensation if they suffer harm as a result of receiving cross-border healthcare are in place*";
- The Member state must ensure privacy and protection of personal data transferred between Member States when ensuring continuity of care by such data transfer; and
- Member States must ensure that all patients, whether from within or without the State are treated in a non-discriminatory manner to avoid "*either perverse incentives to prioritise patients from abroad ahead of domestic patients, or long-term undermining of capital investment in health*".

3.4 Chapter III of the Draft Directive – Use of Healthcare in Another Member State

3.4.1 Social Security Systems

Chapter III of the Directive clarifies that the only social security system involved is that of the Member State where the patient is insured and the only entitlements are those provided in accordance with it. The draft Directive does not change the rights of Member States to define the benefits that they choose to provide and if a Member State does not provide a particular treatment for citizens at home, the draft Directive does not create a new entitlement for patients to have such a treatment abroad. However, it does not prevent Member States from extending their benefits-in-kind schemes to healthcare provided abroad[18].

The draft Directive does not introduce a general *prior authorisation* requirement but treats non-hospital and hospital care differently in this regard. With regard to *non-hospital* care, and in the light of the case-law of the EU Court of Justice, it is believed that there is no evidence to suggest that demand for such cross-border non-hospital care "*will undermine either the financial sustainability of health and social security systems or the organisation, planning and delivery of health services*" and therefore a prior authorisation requirement by a Member State would represent an obstacle to free movement and "*is not justified*"[19].

3.4.2 Prior Authorisation (Non-Hospital and Hospital Care)

With regard to *hospital care*, the draft Directive, in Article 8(1), introduces a minimum Community definition of such care as that requiring at least one night of stay in a hospital or clinic and also potentially including other forms of treatment and "*a regularly updated technical list of such treatments may be specifically defined by the*

2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, p 11-12

[18] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 7.1, p 13

[19] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 7.2, p 15

Commission"[20]. With regard to prior authorisation for *hospital care* the draft Directive allows Member States to provide for a system of prior authorisation for assumption of costs for hospital care provided in another Member State, only in situations where evidence can be provided that the following conditions are met[21]:

- "*had the treatment been provided on its territory, it would have been assumed by its social security system*"; and
- "*the consequent outflow of patients due to the implementation of the directive seriously undermines or is likely to undermine the financial imbalance of the social security system and/or the …planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member*".

3.4.3 Procedural Guarantees

According to established case law, any administrative procedures or decisions that the access to cross-border provision of healthcare services is made subject to are deemed obstacles to free movement of services, "*unless they are objectively justified, necessary and proportionate*"[22].

3.4.4 Information for Patients and National Contact Points

The draft Directive sets out the requirements for essential information to be provided to patients regarding cross-border healthcare and in order that such information is easily accessible to provide national contact points for cross-border healthcare[23].

3.4.5 Rules Applicable to Healthcare Services

To provide clarity on this issue for patients, and "*given that in accordance with the Treaty art. 152.5 the organisation and delivery of health services and medical care rests upon Member States, the rules applicable to the actual provision of healthcare (as defined in Art. 4a) of the Directive has to be governed by the rules of the Member State of treatment*"[24].

3.5 Chapter IV of the Draft Directive – Cooperation on Healthcare

3.5.1 Duty of Cooperation

[20] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 7.3, p 16

[21] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum,7.1, p 14

[22] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 7.4, p 16

[23] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum,7.5, p 17

[24] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 7.6, p 18

It is accepted that the national, regional and local administrative practices in the healthcare sector differ significantly, however the proposed Directive requires that Member States "*render mutual assistance necessary for achieving implementation of the Directive*" with the aim of achieving the potential of the internal market in this sector[25].

3.5.2 Recognition of Prescriptions Issues in Another Member State

The Commission believes this recognition of prescriptions should be possible as "*medicinal products licensed within the community all have to meet harmonised standards of quality, safety and efficacy*" and that systems should be put in place to verify prescriptions issued in another Member State, identify the pharmaceutical product and ensure the patient understands the information required to safely use the prescription. It is accepted that certain categories of medicines may need to be excluded[26].

3.5.3 European Reference Networks and Health Technology Assessment

The proposed Directive provides for the establishment of European networking for centres of reference to maximise the speed and scale of transfer of innovation and providing high quality and cost-effective care across the EU. In addition it provides for the establishment of the Community network on health technology assessment. Currently there are wide variations and frequent duplication in such assessments, between and within Member States, causing a barrier to the free movement of new technologies in the healthcare sector[27].

3.5.4 E-Health

E-health services mean that cross-border healthcare does not necessarily require either the patient or the professional to physically change countries. The proposed Directive does not seek to impose the introduction of e-health systems or services but aims at ensuring interoperability once a Member State decides to introduce such a system. Currently many different and incompatible technologies are used throughout the Community, thus creating obstacles to cross-border service provision in e-health[28].

3.5.5 Data Collection

The proposed Directive provides for Member States to collect statistical and other data to monitor the provision of cross-border healthcare and enable long-term assessment and management of such healthcare[29].

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[25] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 8.1, p 18

[26] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 8.2, p 19

[27] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 8.3, p 19

[28] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final, 2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 8.4, p 20

[29] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare, Brussels 2.7.2008, COM(2008) 414 final,

4. Potential Impact of the Directive

4.1 Potential Impact According to the EU Commission

The Commission believes that the volume of cross-border healthcare will not have a major impact on health systems as it estimates that "*around 1% of public healthcare budgets are spent on cross-border healthcare, equating to around €10 billion for the Community as a whole*". However, it is recognised that the share may be higher in border regions, for smaller Member States, for rare diseases and for tourist areas[30]. The Commission impact assessment,

> "*shows that the additional costs of treatment would be a small fraction of one percent of overall health expenditures, and far outweighed by the benefits. And if in the short term an unpredictable surge of cross-border healthcare were to cause a major problem…the proposal allows Member States to put in place limits necessary to safeguard their overall system*"[31].

For citizens, the Commission proposes that the main benefit the Directive will bring is "*added value*" in that it will provide clarity about the rights, already established by the Court of Justice (interpreting the Treaty), *"conferred to patients when they seek the healthcare, to which they are entitled from providers in other Member States and how they are reimbursed*"[32]. Other benefits for the EU citizen will stem from the proposed European reference networks enhancing expertise in new therapeutic fields and the improved cooperation on the management of new health technologies. Using the Directive will not allow citizens from abroad to be treated more quickly than domestic patients and all patients should be integrated to waiting lists on the same basis "*and should wait as long as a domestic patient with a similar health need*"[33].

Health professionals should benefit from clearer rules about the quality and safety standards to be applied when treating patients from other Member States or when they provide services to other Member States. It will make clear "*that regardless of the status of the healthcare professional, the rules applicable to healthcare are those of the country of treatment (meaning the country where the care is provided)"*[34].

4.2 Potential Impact and Issues for the UK

4.2.1 UK Consultation

The Department of Health has coordinated the UK Government's consultation process on the proposed Directive through its consultation entitled *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare* (consultation closed 3 December 2008)[35]. It is envisaged that Health Departments in England, Wales, Scotland and Northern Ireland would be using this consultation to seek views across the UK and subsequently form one UK negotiating position.

2008, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com_en.pdf, Explanatory Memorandum, 8.6, p 20

[30] A community framework on the application of patients' rights in cross-border healthcare, Communication from the Commission, Brussels 2.7.2008, COM(2008) 415 final, page 8, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com2008415_en.pdf

[31] Communication from the Commission, Brussels 2.7.2008, COM(2008) 415 final, page 9, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com2008415_en.pdf

[32] Communication from the Commission, Brussels 2.7.2008, COM(2008) 415 final, pages 8-9, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com2008415_en.pdf

[33] Communication from the Commission, Brussels 2.7.2008, COM(2008) 415 final, page 10, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com2008415_en.pdf

[34] Communication from the Commission, Brussels 2.7.2008, COM(2008) 415 final, page 9, http://ec.europa.eu/health/ph_overview/co-operation/healthcare/docs/com2008415_en.pdf

[35] www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029

Some of the specific points of relevance to the UK, discussed in the Consultation document and the accompanying Partial Impact Assessment are outlined below. Overall the UK Government welcomes the draft Directive as a means of clarifying the patient's rights that case law has established and also agrees that entitlement to reimbursement for treatment should be limited to the level which the NHS would have paid for the treatment.

The Impact Assessment notes that it is difficult to predict how many people from the UK may seek healthcare in another Member State and vice versa[36],

> "*Evidence from research and overseas treatment schemes …suggests that there will be a very low uptake, at least in the few years after the Directive is finalised. This is because patients tend to express a preference for treatment near home and because the UK provides a comprehensive health service free at the point of need…Similarly, it is difficult to anticipate the number of patients from other Member States that might seek treatment in the UK. Again, evidence suggests that few people currently travel between mainland Member States for healthcare. This might suggest that a low number would come to the UK for treatment given the additional cost and inconvenience of travelling to get here*".

There will be patients living in other Member States with "*retained rights to NHS treatment*" and they will benefit from the proposed Directive by receiving treatment closer to home for those that would have otherwise returned to the UK and possible cheaper treatment for those who otherwise paid locally[37].

4.2.2 Impact of Common Principles in all EU Health Systems

With regard to common principles, the meaning of the draft Directive for an NHS patient who chooses to go to another country for treatment will be that the legislation and standards that apply will be those of the other country and not those of the NHS[38].

With regard to applying the same administrative requirements and eligibility criteria for patients wishing to travel to another Member State, as would be required for accessing the same treatment as home, within the UK, "*this should mean that a patient has to be advised by a GP or other appropriate healthcare professional first (as the 'gatekeeper') to establish clinical need for further specialist treatment and determine NHS entitlement*"[39]. The NHS will be wishing to ensure that "*the 'gatekeeping' function remains fit for purpose in respect of patients who are seeking (what the NHS currently classes as) secondary/specialist care in another Member State*" to ensure that the treatment proposed is appropriate[40].

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[36] *Impact Assessment of EU Commission's Proposals for legislation on patients' rights in cross-border healthcare*, Department of Health, 6 October 2008, page 5

[37] *Impact Assessment of EU Commission's Proposals for legislation on patients' rights in cross-border healthcare*, Department of Health, 6 October 2008, page 10

[38] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008*, www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 14

[39] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008,* www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 20

[40] *Impact Assessment of EU Commission's Proposals for legislation on patients' rights in cross-border healthcare*, Department of Health, 6 October 2008, page 11

With regard to Article 5 of the draft Directive, the UK Government believes that it is not clear enough on the extent of EU-wide standards and it believes that such EU-wide guidelines on quality and safety are not necessary for cross-border care as Member States should be best placed to set such standards for their own health systems[41].

4.2.3 Definition of Hospital Care

As has already been described, the draft Directive defines 'Hospital care' as that requiring an overnight stay or is healthcare included on a defined list of treatments. The Department of Health believes that the proposed Directive is not clear enough on how these principles will be put into practice[42].

4.2.4 Impact of Use of Healthcare in Another Member State

Under the draft Directive citizens will have to pay up-front for treatment obtained in another Member State and this may have equality implications as the "*UK Government recognises that many people may not be able to afford to pay the costs of treatment in the EU up front and then seek reimbursement*"[43]. Despite the fact that reimbursement is limited to the cost the NHS would have paid had the patient been at home the Directive may create costs for the NHS in other ways, for example[44]:

- Paying for treatment earlier than it would have been available on the NHS;
- Paying for dental treatment of patients who travel to receive dental care who have been having no dental care or paying for their own private dental care at home;
- Increased planning costs; and
- The cost of data collection and sharing required by the Directive.

4.2.5 Impact of Patients coming from other Member States to the UK for Treatment

The Department of Health consultation notes that the proposed Directive does not allow the home health system to discriminate against patients accepted from other Member States. It is understood by the Department of Health that receiving Member States are not obliged to accept a patient from abroad to the detriment of domestic patients with similar health needs, however the Directive does not seem clear on the grounds for such refusal. Once accepted there can be no discrimination in favour of a home patient versus a patient from another Member State if both have the same clinical need[45].

4.2.6 Impact of Cooperation on Healthcare

Article 14 of the Draft Directive provides for measures to facilitate recognition of prescriptions. The UK Government has already amended legislation to allow, from November 2008, UK pharmacists to dispense a prescription-only medicine "*in*

[41] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008*, www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 47

[42] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008*, www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 25

[43] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008*, www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 53

[44] *Impact Assessment of EU Commission's Proposals for legislation on patients' rights in cross-border healthcare*, Department of Health, 6 October 2008, page 9

[45] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008*, www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 29-30

response to a prescription written by a doctor or dentist who legally practises medicine or dentistry in another EEA State or Switzerland"[46].

Other practical issues of concern to the NHS are[47]:

- Establishing the costing of treatments – for some services it will be difficult to establish costs. (If the NHS is unable to cost certain treatments objectively it may be required to reimburse full costs of the treatment received in another Member State with the potential to increase the cost to the NHS[48]).
- Difficulties relying on patient records which are not in English;
- The scope of provisions relating to e-health are wide in the draft Directive and need clarification; and
- Data collection requirements may lead to additional costs for the NHS

4.2.7 Professional Opinion

The British Medical Association (BMA) has welcomed the proposed Directive and agrees with the principle of cross-border patient mobility. The BMA also welcomes the emphasis on quality and safety and encourages "*the introduction of a set of minimum quality standards for healthcare in Europe, overseen by the European Commission, in order to ensure the highest possible level of healthcare across the continent*"[49]. This view is in apparent contrast with that expressed by the UK Government in the Department of Health consultation document with regard to such EU standards as discussed in section 4.2.2 of this paper.

The BMA make the following points with regard to the practical implications for the UK[50]:

- It has concerns over continuity of care for patients, based on language problems and different decision-making procedures, especially for certain illnesses where the importance of the established clinical relationship built over time "*cannot be overestimated*" e.g. mental health problems and chronic physical disability;
- With regard to equity:
    - Under current NHS arrangements UK patients cannot access treatment, as a matter of right, in another part of the UK where waiting times are shorter, yet they would be able to seek such treatment in another EU country[51]. This is viewed as anomalous and inequitable for those who could travel to another part of the UK but not further;
    - Patients in greater clinical need with the same condition could have their treatment delayed in the UK if reimbursement of those, from lower down a waiting list who went abroad, prevented the treatment of those in the UK due to lack of funds; and

[46] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008,* www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraph 36-37
[47] *Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare, Department of Health, October 2008,* www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029, paragraphs 54,55 59, 60
[48] *Impact Assessment of EU Commission's Proposals for legislation on patients' rights in cross-border healthcare,* Department of Health, 6 October 2008, page 12
[49] BMA Submission to House of lords EU Committee Inquiry on cross border health care Nov. 2008, www.bma.org.uk/ap.nsf/Content/HoLEUCommInqrossborder
[50] BMA Submission to House of lords EU Committee Inquiry on cross border health care Nov. 2008, www.bma.org.uk/ap.nsf/Content/HoLEUCommInqrossborder
[51] NMC responds to EU Directive on Cross Border Healthcare, (03/07/2008), www.nmc-uk.org/aArticle.aspx?ArticleID=3230

- The NHS Healthcare Travel Cost Scheme could pose an issue as "*qualifying patients would be eligible for this if they were treated in the UK, it would be discriminatory to refuse the reimbursement if they travelled outside of the UK for treatment*".

The Nursing and Midwifery Council (NMC) "*urge the Commission to put patient safety above all other considerations*". The NMC wish the Commission to establish a "clear system of redress for patients who have received unsatisfactory care in another Member State" and would also like to see further steps being taken "*to compel competent authorities to share information about nurses and midwives who are, or have been, subject to disciplinary proceedings*" and "*all regulators to be required to inform their EU colleagues proactively when professionals have been struck off*". As the UK is among only a small number of EU countries to train nurse and midwife prescribers, the NMC is seeking clarification that the Directive will compel relevant authorities to recognise prescriptions signed by authorised prescribers on the NMC register.

5. EU Cross-Border Healthcare – A Sample of Projects

The Health ACCESS project examined whether cross-border arrangements between different countries had the potential to alleviate some of the problems of access to healthcare for the populations within 10 EU countries[52]. Six hurdles that impact on access to healthcare were studied, (i) population covered for health insurance, (ii) benefits covered, (iii) cost-sharing arrangements, (iv) geographical barriers, (v) organisational barriers and (vi) utilisation of accessible services. The following information is summarised, with some extracts, from the Summary and Policy Recommendations of the project's final report[53].

Geographical considerations were most often cited in the study as the reason for cross-border healthcare arrangements and the conclusion was that "*policy makers should seriously consider whether…the right to access health care should not automatically be extended to foreign providers if they are geographically closer or are delivering the service at a higher quality*". Organisational barriers, such as domestic waiting list problems, mean that Member States "*have to make a clear decision whether to send patients abroad or to address problems at home by investing in adequate human and/or infrastructural capacities*".

With regard to the population covered for healthcare, the study revealed that it was important to look beyond the coverage in a 'legal sense' as coverage "*remains a national issue i.e. those not covered inside a country cannot benefit from cross-border arrangements", for the coverage excluding certain groups in some cases, for example refugees. It therefore remains the task of Member States to ensure that population coverage is both legally and de facto universal*". Benefit packages (listing services covered and those excluded) have become more diverse between countries and as they are currently decided nationally "*arrangements for patients to receive explicitly exclude services under public funding elsewhere basically do not*

[52] Republic of Ireland, UK, Netherlands, Poland, Germany, Belgium, France, Austria, Hungary
[53] Busse, R. et. Al. (2006) *Mapping Health Services Access: National and Cross-Border Issues (HealthACCESS),* Final Report, November 2006, http://ec.europa.eu/health/ph_projects/2003/action1/docs/2003_1_22_frep_en.pdf

exist…[forcing] patients to use the E111 procedure by pretending that the need for such a service has arisen while visiting another country".

Within the study, patients' cost-sharing requirements were only rarely given as a reason for the existence of cross-border arrangements as "*such a diversion of care …may increase inequities*". For example, where a provider attracts patients from other countries as the service required is cheaper than in the home country and requires substantial cost-sharing from the patient (e.g. dental care provided in Hungary for patients from Austria). With regard to the acceptability of available services, the provision of more choice via a cross-border arrangement may, as for cost-sharing driven patient mobility, increase inequity "*already seen for specialist care in most countries*" and "*increase, or create, access problems in the receiving country*".

A project entitled The Patient Bridge[54] was initiated in 2000 by the Norwegian Parliament to treat Norwegian citizens at hospitals in Sweden, Denmark and Germany, in response to believed "*capacity constraints in the public health sector, combined with long waiting lists for several groups of patients*". It revealed that although physicians were resistant to the project, the Norwegian patients were willing to undertake travel for treatment in order to reduce their waiting time. Lessons learnt included that "*too many patients with minor illnesses were sent abroad*" leading to relatively high patient transport costs "*and the distribution of patients across foreign hospitals was done without paying sufficient attention to hospital price differentials*".

A European Survey on the potential for electronic prescriptions in cross-border healthcare revealed that only 5 out of the 12 countries studied used or planned to use e-prescriptions, with e-prescribing being most advanced in Northern Europe. The survey concluded that in the countries studied decisions regarding e-prescribing have been made without coordination and "*this is a major drawback in cross-border health-care, where seamless systems and standardized formats would be of prime importance*"[55].

6. Cross-border Healthcare between Northern Ireland and the Republic of Ireland

6.1 Cooperation and Working Together (CAWT)

Cooperation and Working Together (CAWT) is a cross-border body formed in 1992 to improve health and well-being of the population of Northern Ireland and the Republic of Ireland, with particular emphasis on the border. The current CAWT partners are Southern Health and Social Services Board (SHSSB), Western Health and Social Services Board (WHSSB), Health Service Executive (HSE) Dublin North East and HSE West. The eight CAWT strategic objectives for 2007-2013 outline the overall direction that cross-border healthcare is hoped to move over that period. The objectives listed below are extracted from the Executive Summary of the Strategic Development Plan for CAWT, 2007-2013[56]:

> *"1) To improve the health and wellbeing of the population of the island of Ireland with a particular emphasis on the border;*

[54] Botten, G. et. al. (2004), Trading Patients, Lessons from Scandinavia, *Health Policy* **69**, (2004), 317-327
[55] Makinen, M. et. al. (2006), A European Survey on the Possibilities and Obstacles of Electronic Prescriptions in Cross-Border Healthcare, *Telemedicine and e-Health*, **12**(4), 484-489
[56] www.cawt.com/site/default.asp?CATID=455

2) To continue to have a focus in assisting border areas in addressing their distance from the centre of Government including addressing obstacles to cross border mobility;
3) To acknowledge that the next stage in the development of CAWT requires a change in the strategic emphasis in both geographic and service remit which includes a more integrated approach to health provision on the island of Ireland;
4) To play a facilitating role in the provision of population based island health care and in particular contribute to the debate to achieve enhanced service provision and patient satisfaction;
5) To exploit the opportunities of joint working or sharing of resources particularly through the following:
(i) Engagement with the wider European community;
(ii)Engagement with other public sector, community or voluntary initiatives; and
(iii) Better engagement with the providers of care.
6) To identify opportunities for co-operation in the planning and provision of services, particularly the sharing of best practice;
7) To promote and facilitate better engagement with users and patients; and
8) To seek to influence Government policy in respect of planning and provision of health and social care on a cross border basis and in particular promote cross border mobility issues".

Having identified the eight strategic objectives, the CAWT Strategic Development Plan also outlines the priority areas for cross-border development as acute hospital services, chronic disease management, health promotion and well-being, primary community and continuity care, disability and emergency planning[57].

CAWT acknowledges the following views and recommendations of a paper produced for the Centre for Cross Border Studies in February 2006 as having relevance to its Strategic Development Plan[58]:

- *"The reform programmes, north and south could have important impacts on current and potential cross border co-operation on the island. In both jurisdictions the reforms provide a focus on patient outcomes, integration between different levels of care, partnerships between all sectors, strengthening of primary care and centralisation of services.*

- *Within the extensive documentation produced by influential reports for the two reform programmes there is no specific reference made to the implications of change for cross border health care, or the potential that cross border health care offers. This would suggest that the concept of cross border working and planning for health is not yet embedded in the overall context of reforming the health service.*

- *Patient and professional mobility has been much less than expected and the model of cross border service development remains untested.*

- *The greatest potential for cross border co-operation could be in secondary care where there are persistent and growing problems in both jurisdictions in maintaining the viability of small hospitals.*

[57] Strategic Development Plan for CAWT 2007-2013, Executive Summary, paragraph 1.4, www.cawt.com/site/default.asp?CATID=455
[58] Strategic Development Plan for CAWT 2007-2013, Executive Summary, paragraph 1.4, www.cawt.com/site/default.asp?CATID=455, page 29, paragraph 550

- *There is a continued need to undertake research to provide evidence of the value of cross border co-operation and to compare the effectiveness of the two health systems*".

6.2 Cross-Border Hospital Care

In 2007 the Centre of Cross Border Studies (referred to above in the CAWT Strategic Plan) published *Removing the Barriers* on Cross-Border cooperation in Hospital Services[59]. The paper notes that both Northern Ireland and the Republic of Ireland are developing strategies focused on concentrating specialist services on a smaller number of hospital sites. However, Northern Ireland places emphasis on travel-time from a consultant-led A&E or obstetric unit, while the main factor in the Republic of Ireland is the size of the catchment population. It is proposed, therefore, that the two strategies are not compatible. For example, if the catchment population criterion was applied in the North there would only be four or five acute hospitals and many people would be more than an hour from the nearest acute hospital.

The authors of the paper offer the following opinion in connection with planning cross-border hospital care[60],

> *"There is clearly scope for…hospital planning and rationalistion exercises in the border region…a fundamental requisite for further work would be to resolve the differences in strategic policy between the two jurisdictions…this would involve a careful examination of whether the catchment population criterion in the Teamwork Report…is really appropriate for a sparsely populated rural region"* and an *"unwelcome reconsideration of the requirement in Northern Ireland for every component of the population…to be within 60 minutes driving time of the nearest inpatient maternity or A&E unit".*

The authors contrast this lack of joint planning to the well co-ordinated plan for the Cerdagne border region between France and Spain, *"a project is now underway to build a cross-border hospital in Puigcerda which will service the population of the entire border region and be jointly planned, funded and managed by the French and Catalan health authorities"*[61].

6.3 Cross-Border Primary Care – The GP Out-of-Hours Project

Having discussed the apparent lack of co-ordination in acute hospital planning above, this section looks at a more successful area of cross-border cooperation in healthcare. In 2005, CAWT secured funding from the EU Interreg IIIA programme to develop two pilot areas along the border where patients could access closer GP Out-of-hours cross-border services or continue to use the service in their own jurisdiction. Based on a survey of people living or working with communities in the border region

[59] Jamison, J. and Butler, B. (2007) Removing the Barriers – An Initial Report on the Potential for Greater Cross-Border Co-operation in Hospital Services in Ireland, The Centre for Cross Border Studies, www.crossborders.ie/cbnews/barriers/php
[60] Jamison, J. and Butler, B. (2007) Removing the Barriers – An Initial Report on the Potential for Greater Cross-Border Co-operation in Hospital Services in Ireland, The Centre for Cross Border Studies, www.crossborders.ie/cbnews/barriers/php, page 24
[61] Jamison, J. and Butler, B. (2007) Removing the Barriers – An Initial Report on the Potential for Greater Cross-Border Co-operation in Hospital Services in Ireland, The Centre for Cross Border Studies, www.crossborders.ie/cbnews/barriers/php, page 23

and the views of the main political parties, the Centre for Cross-Border Studies described the planned GP Out-of Hour's service as[62]:

> *"One example of practical cross-border co-operation addressing all of the critical factors needed for successful collaboration….It is supported by politicians and border communities. It is well resourced and is built on a platform of collaborative primary care expertise developed under the auspices of CAWT…It is systematically finding solutions to a range of administrative obstacles to co-operation".*

[62] Clarke, P. et. al. (2006) Attitudes to the development of cross-border health services: The case of GP Out-of-Hours Services, Final Report, October 2006, Research report produced for the Co-operation and Working Together GP Out-of-Hours Project Board, Executive Summary