

consultation

AUGUST 2008

NO. 1

A European health service?

The European Commission's proposals on cross-border healthcare

Key questions for NHS organisations

The draft proposals aim to clarify the rules around existing rights to get treatment abroad. Key issues for the NHS include:

- What challenges in terms of financial and capacity planning does cross-border healthcare present compared with domestic choice?
- What are the processes used in the NHS for managing access to healthcare and making decisions about what treatment a patient can receive?
- What impacts could there be on NHS services if patients could access the same services abroad without first obtaining permission from their local commissioner?
- In what circumstances would you consider it appropriate to refuse a patient permission to receive treatment abroad?
- How would you go about calculating the costs of NHS treatment for the purposes of cross-border healthcare?
- Do you see any opportunities for your organisation which might result from increased numbers of patients travelling for planned healthcare, either to or from the UK?
- Concerns have been raised about the potential impact of cross-border healthcare in terms of inequalities. Are there any actions the NHS could take to reduce this potential impact?
- Do you have any other observations based on your experiences of patients travelling for planned healthcare (either to or from the UK), which you think are relevant?

The European Commission has published legal proposals on patients' rights to receive healthcare in other European countries. This *Consultation* outlines the key issues covered and seeks views from NHS organisations on the likely implications for the NHS. The proposals will be subject to negotiation at EU level and the NHS European Office will work closely with key European Union (EU) decision-makers throughout the legislative process to ensure that NHS concerns receive due consideration.

Introduction

Historically, the EU has had a very limited role in health policy, with national governments retaining responsibility for the organisation, funding and delivery of healthcare for their citizens.

However, the situation has become more complicated following a

number of cases in the European Court of Justice (ECJ), where individuals have sought reimbursements for healthcare received in another EU country.

These cases were based on one of the fundamental principles underpinning all European law, that people should be free to access services anywhere in Europe. Rules or restrictions that prevent or make it more difficult to access services in another EU country are not allowed, unless there is a strong objective justification for them.

The ECJ concluded that patients should be free to access health services in other European countries, under the same conditions that they would access healthcare at home. However, the ECJ also recognised that health systems must be able to plan services and to maintain their financial balance. In view of this, some restrictions on accessing healthcare abroad could, in some circumstances, be justified.

ECJ rulings are legally binding and each country has to implement them. There are, however, a number of uncertainties around the case law which make it difficult to implement in practice. This is why the European Commission has put forward proposals for a directive¹ with a view to clarifying the present situation.

The proposals will now be subject to a lengthy process of negotiation at EU level so the next few months present a unique opportunity to feed into and influence these discussions.

1. A directive is a European law which must be implemented in all EU countries. The European Commission proposes draft directives, but in order to become law they must be agreed by the European Parliament and the ministers from the national governments.

Content of the proposals

The rationale underpinning the draft proposals is that it should be as easy as possible for those patients who want to access healthcare abroad to do so, subject to the same conditions which apply to accessing treatment at home. Therefore, as well as restating the existing rights established by the ECJ,

the draft proposals elaborate these with the aim of providing greater clarity for both patients and those administering healthcare systems. The draft proposals also seek to put in place measures that will support patients who do seek treatment abroad, for example, by providing clarity over responsibility for quality and safety issues in cross-border situations.

Key points for the NHS in the current draft proposals

- NHS patients would, in most cases, have the right to seek any healthcare that they would have received under the NHS in another EU country and to be reimbursed by the NHS up to the amount that their treatment would have cost the NHS to provide. The patient would normally have to cover travel and other costs.
- The proposals do not give NHS patients rights to any reimbursement towards the cost of treatment that they would not have received under the NHS.
- Patients seeking treatment abroad would be subject to the same conditions applied to accessing treatment in their home system. For example, an NHS patient who wanted to see a specialist would still need a GP referral.
- Prior authorisation systems (where a patient makes a request to be treated abroad before they obtain treatment) could only be compulsory in certain circumstances. Two criteria must be met. Firstly, treatment must require an overnight stay in hospital (there would also be a list of highly specialised, cost-intensive or high-risk treatments to which the same rules could apply). Secondly, the outflow of patients must pose a risk of seriously undermining the planning or financial balance of the health service.
- Clear criteria for when prior authorisation for treatment abroad would be refused must be set out in advance. In any case, prior authorisation could not be refused if a patient was experiencing 'undue delay' in receiving NHS care (based on their individual circumstances).
- For non-hospital care, there is nothing to prevent commissioners from setting up and encouraging patients to use systems for establishing what reimbursements they will be entitled to before they seek care abroad. However, reimbursement could not be made conditional on the use of these systems and patients would be entitled to seek reimbursements for treatment that they have already received.
- A national contact point to provide information on cross-border healthcare to both home and incoming patients would need to be set up.
- There would be new data collection requirements relating to cross-border healthcare.

Many of these points are not new, but simply restate the existing case law.

The draft directive has three parts:

1. It outlines common principles under which healthcare should be delivered in EU countries, including issues such as quality and safety.
2. It sets a specific framework for patients' rights to access healthcare in another EU country and the rules relating to this.
3. It provides a general framework for European co-operation in areas such as e-health and health technology assessment.

This *Consultation* and the questions it asks focus on the parts of the proposals which we think will be particularly important for the NHS, and which there may be scope to influence as the negotiations progress.

Framework for patients' rights to access healthcare in another EU country

The most important part of the draft proposals from an NHS perspective is the section dealing with the rules and processes that will apply for patients who want to seek healthcare abroad.

The text restates the right, established by the ECJ, to access healthcare in another EU country and to receive a reimbursement towards the costs of treatment that the patient would have been entitled to at home. The level of reimbursement is limited to the amount that the treatment would have cost the home system and there is no requirement for the home health system to pay travel, accommodation or other expenses that would not be covered if treatment was provided in the home country. This means that

the patient would normally need to cover these costs, as well as any difference in the cost of their treatment, themselves.

The draft text includes a number of helpful clarifications. It confirms that, regardless of whether it is a patient who travels for healthcare, or a healthcare provider operating in a different country from where they are based, the legislation and requirements that apply on matters such as quality, safety and liability, are those of the country where the healthcare is being provided.

This means that, the standards set by the Care Quality Commission would not apply to treatment provided in other EU countries, even where this treatment was provided to NHS patients. Instead, it would be the provider country's equivalent system for ensuring quality and safety that would apply. Similarly, NHS hospitals treating patients from other EU countries would do so to NHS standards.

The draft text also confirms that it is always the home health system that decides what healthcare is available to their patients, regardless of whether they are treated at home or abroad. The European Commission argues that – in view of this and the limit on the level of reimbursement – cross-border healthcare should be cost-neutral for health systems. However, the impact in terms of financial and capacity planning, both as a result of outgoing and incoming patients, is not clear.

What challenges in terms of financial and capacity planning does cross-border healthcare present, in particular, compared with domestic choice?

Determining what treatment a patient can receive

The draft text recognises that health systems may impose 'conditions, eligibility criteria and regulatory and administrative formalities' on patients seeking healthcare, and that these can equally be applied to patients who are seeking healthcare abroad. This provides scope for such processes as the requirement to get a GP referral for specialist care. We would welcome views from NHS organisations on whether the proposed wording would adequately cover NHS processes for managing access to healthcare and deciding what treatment a patient can receive. In particular, we are interested in decision-making processes for 'exceptional' or 'low priority' treatments.

What are the processes used in the NHS for managing access to healthcare and making decisions about what treatment a patient can receive? Does the wording 'conditions, eligibility criteria and regulatory and administrative formalities' give adequate scope to include these? If not, what is missing?

Determining where treatment can be received

The draft proposals seek to restrict the use of prior authorisation systems – where a patient makes a request to be treated abroad before they obtain treatment – such that they are only used when there is objective justification that they are needed to protect domestic services for the wider population, and not as an arbitrary barrier to prevent patients from getting treatment in another country when they wish to do so.

The draft text says that reimbursement of the costs of non-hospital care cannot be made subject to prior authorisation – hospital care being

defined as treatment that requires an overnight stay in hospital. So patients should be free to travel for most healthcare that does not require an inpatient stay, and apply afterwards to their commissioner for a reimbursement towards their costs.

The text does allow for prior authorisation systems to be compulsory in some circumstances, but two criteria must be met. Firstly, the treatment must require an overnight stay in hospital (there will also be a list of highly specialised, cost-intensive or high-risk treatments to which the same rules can apply). Secondly, the outflow of patients must pose a risk of seriously undermining the planning or financial balance of the health system.

It is difficult to know how health systems will predict the circumstances or services where the outflow of patients would have such an impact. We would welcome input from NHS organisations on the circumstances in which prior authorisation systems may be needed.

What impacts could there be on NHS services if patients could access the same services abroad without first obtaining permission from their local commissioner? Which services in particular could be affected and how?

The draft text requires each country to specify in advance the criteria for the refusal of prior authorisation and we are seeking NHS views on how these could be defined.

It is important to be aware that, in any case, prior authorisation cannot be refused where a patient is experiencing 'undue delay' in receiving treatment under the NHS. There is no definition of 'undue delay' as this will

depend upon the individual circumstances of the patient.

In what circumstances would you consider it appropriate to refuse a patient permission to receive treatment abroad?

Determining costs and the level of reimbursement

It is disappointing that the draft text does not recognise the value that prior authorisation systems can offer to patients in systems such as the NHS, which do not have defined benefits, in terms of providing them with clarity about the level of reimbursement they will be eligible for. Having said this, there is nothing in the draft directive to prevent NHS organisations putting in place voluntary systems for establishing what reimbursements patients will be eligible for before they seek treatment abroad.

As the NHS is based on a system where the vast majority of healthcare is free at the point of use, one of the biggest issues around cross-border healthcare is how to determine domestic costs. The draft text states that each country should have a mechanism for calculating the level of reimbursement a patient is entitled to if they receive healthcare abroad, but the detail of this is left for each country to determine. The text does not address the calculation of costs to be charged to incoming patients. For the NHS, assessing costs may be a particular challenge for services that are not subject to tariff, or where complex packages of treatment are received.

How would you go about calculating the costs of NHS treatment for the purposes of cross-border healthcare – both for incoming and outgoing patients – in particular, for services not subject to tariff?

Other elements of the text

Standards and principles for the delivery of healthcare

The draft text places a requirement on each country to define and implement clear quality and safety standards for healthcare provided in their country. It specifies a set of principles including universality, access to good quality care, equity and solidarity, which are to be taken into account in fulfilling this responsibility, and sets out a number of specific elements to be addressed, including quality monitoring, information provision, complaints and redress, professional liability systems, data protection and the principle of non-discrimination.

We do not expect that this provision, if it remained as drafted, would have significant short-term practical implications for the NHS, as existing arrangements should adequately address these requirements. However, we are concerned that going into too much detail on matters of implementation, like the need for corrective action when standards are not met, could imply a role for the European Court of Justice (ECJ) on issues that should properly be dealt with by national regulators.

Furthermore, the inclusion of abstract values like 'solidarity' risks creating uncertainty and confusion about what is meant in practice, and could result in legal action testing these principles, which we do not think would benefit either patients or health systems.

We will be seeking clarification of the implications of this provision with a focus on maintaining the appropriate division of responsibilities.

Information on cross-border healthcare

The draft text requires each country to make information about travelling for healthcare easily available to interested patients, including by setting up a national contact point for cross-border healthcare to assist both incoming and outgoing patients. It is envisaged that the national contact points would form a network across Europe.

In addition, the draft text also places requirements on each country to collect detailed information on the provision of cross-border healthcare. We are concerned that these requirements could place significant new bureaucratic burdens on the NHS and will be exploring how these can be limited to the minimum necessary.

Framework for European co-operation

The draft text also seeks to promote co-operation on healthcare at European level, including specific provisions on the development of European reference networks to share expertise on highly specialised care, e-health interoperability and assessment of new health technologies.

All of these areas are already the subject of existing co-operation at EU level. However, we will be examining whether it is necessary and appropriate to provide a legal basis for this work and what the implications of doing so might be.

Recognition of prescriptions

The draft text also includes a provision intended to ensure that a prescription written in one EU country can be recognised and filled in any other, subject to a number of safeguards. The UK is already in the process of

amending its legislation to provide for the recognition of prescriptions written in another EU country, and we welcome the possibility of new safeguards, such as the proposal to develop a system to enable pharmacists to check the authenticity of a prescription.

In line with the principle that the home health system decides what treatment a patient can receive, it is important that this provision does not confer any right to receive under the NHS, or be reimbursed for, drugs that would not be provided by the NHS.

Impact on the NHS

The proposals will be subject to a lengthy process of negotiation before they could become law, during which changes may be made. Therefore, it is impossible to say at this stage what the final implications for the NHS will be. This *Consultation* is seeking the views of NHS organisations to help us understand the likely impacts. We would also welcome views on the following wider questions:

Do you see any opportunities for your organisation which might result from increased numbers of patients travelling for planned healthcare, either to or from the UK? What conditions would help realise these opportunities?

Concerns have been raised about the potential impact of cross-border healthcare in terms of inequalities. Are there any actions the NHS could take to reduce this potential impact?

Do you have any other observations based on your experiences of patients travelling (either to or from the UK) for planned healthcare which you think are relevant?

The NHS European Office will be developing a position drawing on NHS responses and working closely with EU decision-makers to ensure that these issues receive proper consideration.

It is important to understand that the principles laid down by the ECJ, for example, that patients should be able to seek treatment in another EU country, cannot be changed through amendments to the draft directive. This is because they are based on the principle of freedom of movement, which is one of the fundamental rules that underpin all EU law. There is however scope to influence the elements of the draft directive that interpret the case law with the aim of providing clarity or aiding implementation.

In the meantime, the current legal framework, based on ECJ case law, will continue to apply and NHS organisations need to be able to respond appropriately to patients who may be interested in receiving treatment abroad or coming to the UK for the purpose of receiving healthcare.

The process of negotiation in Europe has already started and will continue over the next few months. In view of this, we would welcome views on this *Consultation* and the questions it asks as soon as possible, and at the latest by 14 November 2008. There are likely to be further opportunities to contribute after this date, but, as the proposals may be amended, the focus of discussions may change. Please email your views to helena.bowden@nhsconfed.org

Long-term impacts

It is impossible to predict how patterns of cross-border healthcare will change in the future. However, we know that most patients prefer to be treated as close to home as possible, and it is therefore likely that few patients will seek healthcare abroad unless they perceive that by doing so they can access something 'better' than they would get at home.

The European rules do not allow patients to be reimbursed for treatment abroad that they would not have got at home, so 'better' in this sense is most likely to relate to standards of quality and safety, and issues like cleanliness and waiting times. In a sense then, some of the challenges and opportunities presented by European rules may be similar to those arising from the domestic choice agenda.

The current rules

- NHS patients are entitled, subject to some conditions, to receive care in another EU country and NHS commissioners should have a system in place to deal with requests for treatment abroad. Usually the patient will need to pay for their treatment up front and then claim a reimbursement from their NHS commissioner.
- If undue delay applies to NHS care, a request for treatment abroad cannot be refused.
- Patients can only receive reimbursements for treatment that their commissioner funds.
- Prior authorisation systems can be used, but can only be compulsory in certain circumstances, usually for care that requires a stay in hospital. Where prior authorisation is not compulsory, patients can ask for refunds of costs of planned treatment already received in another EU country.
- These rules all relate to planned care. They do not affect the existing European Health Insurance Card (EHIC) provisions, which provide for EU visitors to another EU country to receive emergency or immediately necessary treatment under the same conditions as local patients.

More information on the current rules can be found on the NHS European Office website at www.nhsconfed.org/euunit/euunit-3874.cfm

The NHS European Office

The NHS European Office has been established to represent NHS organisations in England to EU decision-makers. The office is funded by the Strategic Health Authorities and is part of the NHS Confederation.

EU policy and legislation have an increasing impact on the NHS as a provider and commissioner of services, as a business and as a major employer in the EU.

Our work includes:

- monitoring EU developments which have an impact on the NHS
- informing NHS organisations of EU affairs
- promoting the priorities and interests of the NHS to European institutions
- advising NHS organisations of EU funding opportunities.

NHS European Office

Rue Marie Thérèse, 21, B-1000 Brussels
Tel 0032 (0)2 227 6440 Fax 0032 (0)2 227 6441
Email european.office@nhsconfed.org
www.nhsconfed.org/europe

This document is available in pdf format at www.nhsconfed.org/publications

© NHS Confederation 2008. Registered Charity no: 1090329

EUR00301