

# briefing

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## Patient choice beyond borders

### Implications of the EU Directive on cross-border healthcare for NHS commissioners and providers

#### Key points

- The right of patients to receive healthcare in another EU member state, and to be reimbursed by their healthcare system, has been established by several decisions of the European Court of Justice.
- The recently adopted EU Directive will clarify how this right is implemented in practice.
- Many questions arise on how the rules will be implemented on the ground. We will help NHS organisations to understand them and to ensure that their views are heard throughout the implementation process.

An EU law clarifying the right of patients to receive healthcare in other EU member states was adopted in March 2011. This Directive will have the effect of extending patient choice beyond national borders, with significant implications for both NHS commissioners and providers. This *Briefing* provides an overview of the EU rules and their implications for a changing NHS.

#### Background

A proposal for a Directive to clarify the right of patients to receive healthcare in other European Economic Area member states\* was released by the European Commission in summer 2008. The proposal was based on a succession of European Court decisions during the last ten years, where individuals sought reimbursement for healthcare received in another European country.

This included the landmark "Watts" case which concerned the NHS directly. In 2003 Mrs Watts, a UK patient who had gone to France to seek treatment to avoid a long waiting time in the NHS, and had then sought reimbursement of the cost of her treatment from her local primary care trust, had her case referred to the European Court of Justice. In 2006 the court ruled that she was entitled to the treatment and that the NHS should pay because she had suffered

\*The member states of the European Union plus Iceland, Leichtenstein and Norway.

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"undue delay" in getting her treatment.

Taken together, these court cases have established that patients have certain rights in relation to cross-border healthcare. However, there were a number of uncertainties around the case law which made it confusing for patients and difficult for health systems to implement in practice. For example, it was not clear when or if health systems could apply a system of prior authorisation or what levels of reimbursement should apply. The proposed Directive sought to clarify the situation, for the benefit of both patients and those managing health services.

After a lengthy EU decision-making process, the Directive was formally adopted at EU level in March 2011. The NHS European Office engaged significantly with the proposals throughout the process, briefing EU decision-makers on NHS views and ensuring that the rules will not impact negatively on the NHS.

Thanks to our extensive lobbying we are pleased with the agreed text. The Directive will help patients to make informed decisions about cross-border healthcare by providing clarity on matters such as what reimbursements they will be

eligible for and what costs they will have to meet themselves, what quality and safety standards will apply, and what to do if anything goes wrong.

It will also end the uncertainty that commissioners currently face over decisions about what care patients can receive abroad, while allowing the NHS to maintain control over patients' entitlements. On the provider side, the rules will offer opportunities to increase income by providing services to EU patients when capacity allows.

It is worthwhile noting that, alongside this new Directive, a separate EU mechanism for patients to obtain planned treatment in another European country at the expense of their home healthcare system already exists under longstanding EU regulations on the coordination of social security schemes (the 'S2 referral' – formerly known as E112). The difference between the two routes to cross-border healthcare is not always clear cut.

In principle, the Regulation on the coordination of social security schemes<sup>1</sup> governs the following situations: health cover of UK nationals who are resident abroad; commissioners' decisions to refer patients to another EU country, for example, if certain treatment cannot be provided in the UK or in case of 'undue delay'; as well as patients needing emergency care during a stay abroad.

The new Directive, reflecting freedom of movement principles under the EU Treaty, goes further. It provides a legal framework to apply to situations where a patient

takes a personal decision to travel abroad to receive healthcare.

## Key provisions in the EU Directive

The rationale underpinning the Directive is that it should be as easy as possible for patients who want to access healthcare abroad to do so, subject to the same conditions which apply when accessing treatment at home. Therefore, as well as restating the existing rights established by the European Court of Justice, the Directive builds on them to provide clarity on the rules and processes applicable for patients who want to seek healthcare abroad.

Alongside this, the Directive encourages cooperation between member states in a number of areas related to cross-border healthcare, such as:

- the recognition of medical prescriptions filled out in other member states
- cooperation between providers, especially in the area of rare diseases
- the use of e-health for the transfer of patients' records between countries
- the assessment of health technologies.

The provisions in the Directive of key importance from an NHS perspective are outlined below.

## Determining what treatment a patient can receive

The Directive clarifies the rights that patients have to

access healthcare in another European country and to receive reimbursement towards the costs of treatment that the patient would have been entitled to at home. It confirms that it is always the home health system that decides what healthcare is available to its citizens, regardless of whether they are treated at home or abroad.

It also recognises that patients wishing to receive cross-border healthcare can be subject to the same 'formalities' as patients seeking healthcare in the NHS. This would include, for example, requiring that a patient seeks GP referral to access specialist care. This provision is particularly important for the NHS which, as opposed to social insurance systems, does not have a basket of healthcare to which all patients are entitled, but rather makes decisions on eligibility locally, taking into account the circumstances of individual patients.

### Authorising patients to receive treatment abroad

The Directive allows member states the option of introducing a system of prior authorisation

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for patients seeking cross-border healthcare. Prior authorisation is only possible for healthcare which is subject to planning requirements and which involves at least one night in hospital, or requires the use of highly specialised and cost-intensive medical equipment. Authorisation can only be refused in limited circumstances listed in the Directive and decisions have to be taken in an objective and non-discriminatory manner. For example, authorisation could be refused when the patient would be exposed to a very high safety risk that cannot be regarded as acceptable.

It is important to emphasise that authorisation cannot be refused where a patient is experiencing 'undue delay' in receiving treatment under the NHS. While there is no formal definition of 'undue delay', the European Court has stressed that judgments must be based on a clinical assessment of what is a medically acceptable period for the individual clinical circumstances of the patient, and that this assessment needs to be kept under review while the patient is waiting for treatment. Significantly, the European Court has said that offering treatment within a national waiting time target does not necessarily avoid 'undue delay'.

For other types of healthcare, a voluntary system of prior notification can be introduced to encourage patients to inform their commissioners of their intention to receive healthcare abroad and to discuss what reimbursements they will be entitled to. It should be noted,

**'Commissioners will not be required to pay more than the cost of that treatment if provided by the NHS'**

however, that reimbursement cannot be made conditional on the use of this system and patients will still be entitled to seek reimbursements for treatment that they have already received.

### Determining costs and the level of reimbursement

Under the Directive, patients can seek any healthcare (including private care) in another European country that is the same as, or equivalent to, a service that would have been provided to the patient under the NHS. The Directive allows for two possible systems of payment of cross-border healthcare costs: either patients pay up-front and are then reimbursed by their local commissioners; or commissioners pay the provider abroad directly.

In any event, commissioners will not be required to pay more than the cost of that treatment if provided by the NHS. Furthermore, there is no requirement for commissioners to pay travel, accommodation or other expenses that would not be covered if treatment were 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. Nevertheless, commissioners may decide to pay additional related costs, such as accommodation and travel costs, for individual patients.

**'In the event that waiting times were to increase for certain treatments under the NHS, we could expect a larger number of patients seeking cross-border healthcare going forward'**

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 text states that each country should have a transparent 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.

For healthcare which is not covered by an NHS tariff, defining the level of reimbursement could be particularly challenging when prices are set by commissioners or subject to negotiations between commissioners and providers, and therefore subject to significant local variations. Furthermore, a tariff may cover a package of care, rather than a simple procedure, and therefore costs may need to be 'unbundled' if a patient receives a different package of care in another EU country.

Regarding the costs to be charged to incoming patients, the Directive states that providers apply the same tariffs they apply to domestic patients in a comparable medical situation or, when this is not possible, a price calculated on the basis of objective and non-discriminatory criteria.

## Key points for commissioners

- NHS patients have the right to seek in another European country any healthcare that they would have received under the NHS and to be reimbursed by their commissioner up to the amount that their treatment would have cost the NHS to provide.
- The patient pays the difference if care abroad is more expensive. The patient would also normally have to cover travel and other costs, unless their commissioner decides to cover these additional costs on an individual basis.
- The Directive does not give NHS patients rights to reimbursement towards the cost of treatment that they would not have received under the NHS.
- Patients seeking treatment abroad can be made subject to the same conditions that apply when accessing treatment under the NHS. For example, a patient who wanted to see a specialist abroad would still need GP referral.
- Prior authorisation systems (where a patient makes a request to be treated abroad before they obtain treatment) may only be introduced for healthcare which is subject to planning requirements and which involves at least one night in hospital, or requires the use of highly specialised and cost-intensive medical equipment.
- Prior authorisation cannot be refused if a patient is experiencing (based on their individual circumstances) 'undue delay' in receiving NHS care.
- Commissioners have a duty to ensure that patients who receive cross-border healthcare can have access to follow-up healthcare if and as required when they travel back to the UK.
- Commissioners may decide to pay directly for healthcare in another European country, if this would benefit the patient.

## Quality and safety standards

The Directive confirms that 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 European 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.

## Analysis of implications for commissioners

Whilst it is impossible to predict how patterns of cross-border healthcare will change in the future, it is broadly recognised that most patients prefer to be treated as close as possible to home and therefore, in principle, we do not anticipate a large expansion in the volume of cross-border healthcare within the framework of the Directive.

Nevertheless, it should be emphasised that one of the main reasons given by patients for seeking cross-border healthcare is the opportunity to receive treatment more quickly. Therefore, in the event that waiting times were to increase for certain treatments under the NHS, we could expect a larger number of patients seeking cross-border healthcare going forward.

As patients may only receive reimbursement for healthcare abroad that they are entitled to receive under the NHS, at a cost which is not higher than the NHS cost, cross-border healthcare

is not expected, in principle, to have major implications for NHS budgets. Nevertheless, as authorisation cannot be refused in cases of 'undue delay', there could be some implications in terms of commissioners' ability to plan and prioritise. This could, in turn, have implications for health inequalities by allowing certain patients to receive treatment more quickly than patients who are in greater medical need.

Another challenge for commissioners relates to determining domestic prices for healthcare, especially for those procedures which are not covered by a tariff and are subject to significant local variations.

On the positive side, the Directive will reduce the uncertainty commissioners currently have on what rights NHS patients have to receive treatment abroad and how to handle requests from patients for cross-border healthcare.

As the NHS is expected to move to a system allowing for greater variation at local level on which treatments patients are entitled to receive, a key issue with the implementation of the EU rules will be to ensure that commissioners have a clear 'list' of which types of healthcare they allow (or do not allow) their patients to receive. This will be crucial to avoid uncertainty for both commissioners and patients, and to reduce the risk of legal challenges from patients trying to access treatments abroad which are not routinely available under the NHS.

At a time when the UK Government has put forward proposals to extend patient choice and to diversify providers in the healthcare market, the Directive will have the effect of extending patient choice beyond national borders. It should be emphasised that patients will have the right to access treatment from any healthcare providers abroad, including private sector providers.

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## Information to patients on cross-border healthcare

The Directive requires each member state to make information about travelling for healthcare easily available to interested patients, including by setting up one or more national contact points for cross-border healthcare to assist both incoming and outgoing patients.

The role of national contact points is to provide patients, on request, with information on their entitlements to healthcare or procedures for accessing and determining entitlements. They will also be required to provide information on the quality and safety standards that apply in their country and a list of the providers which are subject to them. Furthermore, they should provide

## Analysis of implications for providers

Future demand in the area of cross-border healthcare is difficult to assess due to the very limited information on the current levels of cross-border healthcare in Europe. In the short term, it will take time for the Directive to bed in, for the rules to be understood, and for the message to get out to the public. It is, however, possible that the UK could see requests from more European patients for access to treatment in some clinical areas, where perhaps there are capacity issues in their home countries.

In the current economic climate, NHS trusts may be interested in exploring opportunities to provide health services to European patients to diversify their income. Opportunities could emerge, in particular, for those trusts which provide highly specialised care and have an international reputation. In such cases, it is key that sufficient capacity is planned, so that additional patients can be treated to the benefit of, and not

the detriment of, NHS patients.

The proposed removal of the private patient income cap, which currently reduces the ability of some foundation trusts to treat a greater number of non-NHS patients, will allow these trusts to take full advantage of the opportunities emerging from the EU rules. It should be noted, however, that European patients must not be automatically classed as private patients, as this would be discriminatory and contrary to EU law. Providers will instead have to offer these patients the option to be classed as 'paying' NHS patients or private patients, with only the latter being subject to private fees.

It should also be emphasised that NHS tariffs are often higher than tariffs applied in other member states and that this could impact on the ability of NHS trusts to 'attract' EU patients. This is because patients are reimbursed only up to the cost of the same

healthcare in their home country and therefore would have to cover the difference personally whenever NHS care is more expensive.

Opportunities for NHS trusts with specialist expertise, and notably with expertise in the diagnosis and treatment of rare diseases, will emerge from the setting-up of 'European reference networks'. The Directive does not include information on the format and operation of these networks and therefore we are not currently in a position to detail the opportunities which could arise for the NHS. As the networks will concentrate knowledge in medical domains where expertise is rare and foster progress in the diagnosis and treatment of rare conditions, we could, however, expect positive repercussions for participating trusts in terms of international reputation, learning through collaboration with European colleagues and improved patient care.

information on liabilities and complaint procedures in the event that the patient suffers harm.

### Cooperation between providers across Europe

The Directive seeks to promote cooperation between providers

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and centres of expertise through the development of 'European reference networks', notably in the area of rare diseases. These networks will concentrate knowledge in medical domains where expertise is rare and foster progress in the diagnosis and treatment of rare conditions. The European Commission will develop a methodology for the setting up and operation of these networks in the run-up to the implementation of the Directive. We will monitor this process and contribute NHS views to maximise the opportunities for NHS trusts.

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### Next steps

The Directive is the first genuine example of EU legislation specifically in the area of healthcare services, which are

## Key points for providers

- Both NHS and independent and third sector providers can provide healthcare to European patients\* and be paid for this healthcare directly by the patient or through the patient's home system.
- Providers cannot discriminate against European patients by applying different quality and safety standards, or higher charges. This means that these patients cannot automatically be charged private patient fees, but instead have to be given the option to be treated as 'paying' NHS patients or private patients.
- It is not yet clear how the cost of health procedures will be calculated and, in particular, if the NHS tariffs could be topped up to take into account additional costs which would only apply to European patients for objective reasons.
- Providers are liable for the healthcare they provide. This means that European patients who are not happy with healthcare they have received or who have suffered harm will have the right to complain and seek compensation according to UK rules and procedures.
- No provider is required to accept patients from elsewhere in the EU to the detriment of home patients. This is particularly relevant for NHS organisations providing highly specialised services for which a possible surge of incoming patients could lead to negative implications in terms of increased waiting times for NHS patients.

\*Patients from the member states of the European Union plus Iceland, Leichtenstein and Norway

- collected by NHS commissioners and providers
- how the cost of cross-border healthcare will be calculated, in particular for those procedures which are not subject to NHS tariffs.

The Department of Health will lead on the implementation process on the basis of guidelines to be released by the European Commission to assist member states. The Department intends to consult on plans for implementation of the Directive later this year. The NHS Confederation and the NHS European Office will monitor both domestic and EU developments and engage with them on behalf of our members. We will continue to keep NHS organisations informed of developments and assist them in making sense of the new rules and their implications.

Until the new Directive is implemented into national law, the existing rules on cross-border healthcare, established in a number of European Court cases, remain in force and it is important that NHS organisations are aware of these. The Department of Health has published regulations, directions<sup>2</sup> and guidance on the establishment of prior authorisation and reimbursement arrangements for NHS patients seeking treatment under the cross-border rules, which local commissioners should continue to apply in the interim.

For more information on the issues covered in this *Briefing*, contact [elisabetta.zanon@nhsconfed.org](mailto:elisabetta.zanon@nhsconfed.org)

traditionally the sole preserve of national governments.

The Directive will have to be implemented in the UK by October 2013. The transposition of the Directive into UK law will take place in parallel to the programme of NHS reforms in England, raising many questions about how the rules will be implemented on the ground and which organisations will be responsible for its different provisions.

It will be during the transposition into UK law that key issues regarding the practical

implementation of the Directive will be decided. This will include, for example:

- decisions around how the process of prior authorisation will work in practice
- how to ensure that patients can access detailed information on their entitlements to healthcare
- how many contact points for cross-border healthcare will be established across the country and which organisations will be responsible for this function
- which data on cross-border healthcare will have to be

## References

1. Regulation EC 883/2004, which repealed Regulation 1408/1971.
2. The NHS (Reimbursement of the Costs of EEA Treatment) Regulations 2010 – S.I. 2010 No.915.  
The NHS (Reimbursement of the Costs of EEA Treatment) (England) Directions 2010.

## 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 healthcare, 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.

To find out more about us, and how you can engage in our work to represent the NHS in Europe, visit [www.nhsconfed.org/europe](http://www.nhsconfed.org/europe) or contact [european.office@nhsconfed.org](mailto:european.office@nhsconfed.org)

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