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EU Briefing

EHMA
European Health Management Association

A BRAVE NEW WORLD? EU ADOPTS CROSS BORDER CARE DIRECTIVE

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1. Background

On 19 January 2011, the European Parliament voted in a second reading in favour of the draft EU Directive on Patients Rights in Cross Border Care. The European Parliament vote paves the way for the Directive to be transposed into national law. This adoption of the Directive is a historic step for EU health policy making, particularly given the length of time the draft Directive – first published in 2008, but with a long history dating back to the 1990s – has been under discussion.

The final draft voted upon by the European Parliament is a compromise text that resulted from several trilogue meetings held between the European Parliament, the Commission and the Belgian Presidency of the EU at the end of 2010 in order to find an ultimate agreement of the draft. The draft differs significantly from initial draft versions of the Directive: with many compromises on controversial issues such as HTA, eHealth regulations and rare diseases.

The briefing will look at some key details covered by the final Directive. It will also look at some unresolved issues and possible implications for member states.

2. Details of the Directive

Who is entitled to cross border care?

All citizens of the EU are able to access planned healthcare in other EU states that they would be entitled to in their own country and are able to be reimbursed for that in their own member state.

For what amount can I be reimbursed?

Patients are able to be reimbursed for the care received abroad, up to the amount the same type of healthcare care would have cost in their own country. This should not exceed the cost of the care actually received. Member states can provide additional funding for travel and accommodation.

Do I need to pay upfront?

Payment of treatment accessed abroad is generally made by the patient upfront which is then reimbursed by their home state. However, allowances are made in the Directive for member states to pay for care abroad directly to the provider.

(When) do I need prior authorisation from my member state?

Patients should not need prior approval from their home state to be entitled to reimbursement for care accessed in another member state. However, states can introduce a system of prior authorisation in a number of cases:

A BRAVE NEW WORLD? EU ADOPTS CROSS BORDER CARE DIRECTIVE

A BRAVE NEW WORLD? EU ADOPTS CROSS BORDER CARE DIRECTIVE

EHMA
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1. Where the care involves an overnight stay in hospital of at least one night
2. For highly specialised and cost intensive healthcare
3. Where the treatment poses a particular risk for the patient or the population
4. Where on a case by case basis there are serious and specific concerns relating to the quality or safety of the care to be provided

How fast can prior approval be given?

The Directive states that decisions relating to prior approval should be made within reasonable time limits. The time limits should be shortened if the treatment is urgent.

Can prior authorisation be refused?

Prior approval can be refused in a number of specific circumstances:

1. The patient or general public will be exposed an unacceptable safety risk
2. There are serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety
3. The healthcare can be provided by the member state within a medically justifiable time limit for that individual.

Who can help me with more practical details on cross border care?

The directive sets out the establishment of national contact points to provide appropriate information to enable people to find out their rights and make informed choices regarding cross border healthcare. They will have to provide compulsory information. Member states can decide on the number and form that the contact point takes. It is envisaged that contact points will share information between them.

What about my medical records?

In line with an individual's right to access personal data concerning their health, patients should have at least a copy of their medical records if they seek to receive or receive cross border healthcare. They should also have at least a copy of written or electronic records relating to the treatment received in another member state. The directive also supports enhanced cooperation, through a network, between member states on ehealth to facilitate the sharing of patient information cross borders.

Are there any treatments excluded from the regulation?

Organ transplantation falls out of the scope of the Directive.

A BRAVE NEW WORLD? EU ADOPTS CROSS BORDER CARE DIRECTIVE

3. Work still to be undertaken

National governments have 30 months to transpose these measures into national organisation. In this transposition period member states will need to ensure that the administrative processes are in place to enable the cross border healthcare to function as described in the directive. Member states are also asked to establish their national contact which could then take part in the European reference network.

In the meantime, the European Commission is to set up networks to facilitate cooperation between states with regards to HTA and eHealth.

4. Issues for debate

The Directive is a very important next step in aligning rulings by the ECJ on cross border care and setting up a legal framework for patients wishing to cross borders for care. Nonetheless, questions remain on some of the more controversial areas of the Directive:

Upfront payment

In most of the cases patients are requested to pay upfront for cross border treatment. As stated in earlier EHMA briefings, this could result in inequity of access to cross border care, making access more difficult to those people without sufficient funds to pay for care. In an earlier roundtable organised by EHMA in 2010, the Techniker Krankenkasse, a German Insurance Fund revealed some important findings regarding the characteristics of their patients making use of cross border care: the majority of the patients were older than 60 years old (79%), and lived on lower incomes (76%). More specifically, 48 percent of the candidates reported to have a monthly gross income of less than 1500 EUR and 28 percent a gross income of between 1500-2500 EUR. If this trend can be extrapolated to European citizens more generally it would mean that problems in terms of upfront payment are possible in the future.

The principle of prior authorisation

In initial drafts of the Directive it was intended to establish a general principle to allow patients to receive non hospital care and hospital care which does not involve overnight stay without prior authorization. This principle has now been softened giving more room to member states to request prior authorisation should there be a risk of seriously undermining the financial balance of the system. As set out in the final Directive, prior authorization is now also required for highly specialised and cost intensive healthcare and for care where the treatment poses a particular risk for the patient or the population. Important here is that no uniform definitions are set in place to define highly specialised and cost intensive healthcare, nor to define when treatments pose a risk for a patient or population. The Directive states that decisions related to the latter are allowed to be taken on a case by case judgement. It can therefore be foreseen that different interpretations and inconsistencies may occur and that it is very likely that new cases are to be brought in front of the European Court of

A BRAVE NEW WORLD? EU ADOPTS CROSS BORDER CARE DIRECTIVE

EHMA
European Health Management Association

Within reasonable time limits...

The final Directive also states that decisions by the national reimbursement bodies relating to prior authorisations should be made within reasonable time limits and that time limits should be shortened if the treatment is urgent. It also states that the bodies can refuse prior authorisation should the same type of care be provided by the member state within a medically justifiable time limit. Here again, no uniform definitions are in place on what "medically justifiable" and "reasonable" time limits just are which may lead to differences in interpretation between member states. The length of time defined within member states to grant prior authorisation could also result in disincentives for people to seek care abroad.

Rare diseases and reimbursement of treatments not available in the country of origin

Rare diseases had always been excluded from the frame of the Directive and came on the agenda relatively late in the process when the European Parliament Health and Environment (ENVI) Committee opted to include Europeans affected by rare diseases under the provisions of the Directive. The ENVI Committee believed that it was a missed opportunity not to include that group of citizens, given that approximately 25 million Europeans are affected by rare diseases.

Since the call to include rare diseases on the cross border care agenda, rare diseases have been one of the most contentious issues of the draft directive. The result here is also a compromise. On the one hand, the Directive supports the development of European reference networks to improve access to diagnosis and treatment for people with rare diseases. The networks would cooperate on a voluntary basis to enable a concentration of resources and expertise as required by this group of patients. On the other hand, there is still some vagueness around the reimbursement of treatments that are not available in the country of origin (i.e. treatments for rare diseases). In theory member states do not need to reimburse those treatments not available in their own country. They can only "do so if they wish".

Cooperation on eHealth and HTA

Also in the fields of eHealth and HTA compromises have been made between the wishes of the European Parliament and Commission and the member states. For eHealth the original draft text contained an Article in which it was mentioned that member states, supported by the European Commission, would aim at interoperability of information and communication technology systems, and the new text has been softened considerably. The eHealth article now focuses on the set up of a voluntary network connecting national authorities responsible for eHealth designated by the Member States. The aim of the network would be to support and facilitate the cooperation and the exchange of information among the member states. The same type of network is envisaged for the field of HTA.

While the set up of the networks are good initiatives to enhance further

A BRAVE NEW WORLD? EU ADOPTS CROSS BORDER CARE DIRECTIVE

exchange of knowledge, membership to those networks remains voluntary.

5. Next steps: on measuring the impact for member states and health managers

The agreement on the Directive is to be welcomed. Although there are many issues not addressed in the text, the existence of a legal EU framework to clarify the position for patients on travelling abroad for planned healthcare is a significant achievement. The choice has not been between a perfect and an imperfect legal framework but between having or not having a legal framework. It is now important to see how member states will transpose the directive into their national frameworks and how it will impact on their laws. It can be expected that some countries will find less difficulties in transposing the Directive than others. This might be because (1) they are up to date with implementing ECJ rulings on cross border care or (2) they have already started writing up plans to implement the outcomes of the Directive or (3) their type of health system might make it easier to implement cross border care regulations. EHMA is particularly interested in the implications the Directive might have for health policy makers and health managers and is planning a number of initiatives. Interested members are invited to contact Annemie Coeme (Annemie.coeme@ehma.org).

- Cross border care simulation: simulating the possible impacts of the Directive in autumn 2011, in cooperation with the European Social Observatory.

- Disseminating the results of a follow up study carried out by EHMA Member the Techniker Krankenkasse to investigate planned treatment in 2010 amongst 40,000 TK insurers and focusing on some additional questions such as the quality of the treatment and the service of the providers; satisfaction with the provider and the treatment, the needs of patients concerning information as well service provision. The results of the new cross border care study will be launched on 20 May 2011 at a European Healthcare Conference at the TK Headquarters in Hamburg.

- EHMA is also planning a policy brief to discuss the implementation of the Directive and the potential impact of the Directive on the daily lives of patients, health professionals and health managers. Any members interested in contributing to the paper are invited to contact Annemie Coeme (annemie.coeme@ehma.org).