European and External Affairs Committee

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Implications for NHS Wales of the proposed Patients' Rights in Cross-Border Healthcare Directive

Purpose

1. This paper has been prepared in response to a request from the Committee for a short paper on this topic in connection with oral evidence to be given by Mr Paul Williams, Chief Executive of NHS Wales.

Background

2. The Patients' Rights in Cross-Border Healthcare Directive is at present being discussed within the institutions of the European Union. This paper offers some considerations on the possible implications here in Wales.

Summary

3. The paper sets out some background on the proposed Directive by way of introduction and possible implications under three heads:

    - changes the NHS will have to make to meet the Directive as drafted;
    - possible changes in patient flows; and
    - consequential impact of these changes on NHS Wales.

4. It concludes that numbers travelling under the proposed Directive may be small, but that there be might be implications in relation to planning and administration and some reduction in funding available for providing services within Wales.

Introduction

5. The Patients' Rights in Cross-Border Healthcare Directive has been drafted by the European Commission in response to a series of judgments by the European Court of Justice (ECJ) that clarified patients' rights to access healthcare in another European Economic Area (EEA) Member State under the freedom to obtain services as set out in Article 49 of the Treaty Establishing the European Union. The EEA States are the European Union countries, plus Norway, Iceland and Liechtenstein

6. Prior to 2006 and the outcome of the Watts Case the United Kingdom (UK) had maintained a position that health services were outside of the competence of the EU and that previous ECJ judgements were not applicable to NHS type systems. The ECJ ruling in the Watts Case confirmed that other aspects of EU Treaty law, such as Article 49, did apply to all Member State's health systems and thus previous case law also applied.

7. The judgements, by their nature, have related to the narrow issues before the Court, and left some uncertainty as to the precise position of patients and governments, for example –

   - can Member States protect traditional gate-keeping systems (for example General Practitioners)?
   - what are the rules for refusing prior authorisation?
   - what are the principles of clear and transparent pricing/costing systems?

8. The draft Directive is therefore not an attempt to create new rights for patients, but an attempt to clarify how existing rights under Article 49 work in practice.

9. These judgements came on top of longstanding arrangements around the transfer of social security entitlements, including healthcare, under EU Regulation 1408/71. As part of this, using the E112 form scheme, patients who are resident in the UK can request treatment in another EEA country (and also Switzerland). A patient is entitled to treatment in another EEA country if they face 'undue delay' (as determined by clinical reference to the patient's condition) in obtaining their treatment domestically and the NHS must pay for any treatment received under this scheme.

10. The numbers using this E112 scheme are very low – just 550 across England, Scotland and Wales in 2007 - this gives a strong indication that patients prefer not to travel to receive healthcare.

11. The Commission's proposal has three components:

    1) *Common principles in all European Union health systems* – measures the Commission considers are necessary for cross-border healthcare to operate effectively and for patients to have trust in cross-border healthcare;

    2) *Use of healthcare in another Member State* - the practicalities of cross-border healthcare, e.g who pays, for what, how much; and

    3) *Co-operation on healthcare* - co-operation at an EU level on health matters, e.g. information sharing, European Reference Networks.

12. The Directive is not directly about how States organise and manage their health systems internally. The stated aim is to establish "*a general framework for the provision of safe, high quality and efficient cross-border healthcare*"; the scope applies to "*healthcare regardless of how it is organised, delivered and financed or whether it is public or private*".

13. In effect, the draft Directive will deliver a system which allows patients (under Article 49) to leave their health systems to obtain treatment under the auspices of other Member States' systems.

14. In order to allow patients to secure care safely in other countries, there need to be quality assurance systems in every country as well as mechanisms to enable patients to find both what is available and then to secure an appropriate service. Patients who decide to leave their health systems will not be covered by the duty of care and liability arrangements of the home system; these patients will receive treatment subject the law of the Member State of treatment.

15. The effect of the proposed Directive within Wales is that NHS Wales will, in common with the other health services in Europe, have to adopt some ways of working, to make this approach practically possible.

16. This paper discusses three main sorts of impact on NHS Wales:

    - changes the NHS will have to make to meet the Directive as drafted;
    - possible changes in patient flows; and
    - consequential impact of these changes on NHS Wales.

17. The detail of changes, including the cost and disruption associated with them, are yet to be fully scoped. The paper provides such evidence and insights as are currently available.

18. It is worth noting this draft Directive will be changing throughout these negotiations and Department of Health officials have noted that other Member States appear to share concerns with the UK on key topics.

Changes NHS Wales will have to make

19. Much of the Directive codifies and clarifies the application of existing case law, which is already binding on Member States. If Welsh commissioners currently receive a request from a patient to access healthcare in another Member State, they should refer to the relevant UK wide guidance (issued April 2007) when dealing with this request; this guidance is available on the Department of Health website at jhttp://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073850.

20. However, under the proposals of the draft Directive each Member State, hence Wales as part of the UK, would need to consider future actions (although many of these are effectively requirements in case law following earlier ECJ judgements). Such actions might include:

    a. set healthcare standards which include the monitoring of healthcare providers; the need for complaint systems to be in place; the need for indemnity insurance for providers; and respect for patient privacy; this would require a review in due course of what systems are in place now, but these are broadly in place and UK officials believe UK health systems are likely to meet the requirement.;

    b. establish and advertise prior authorisation arrangements for hospital care in line with the Directive's requirements; this must be necessary and proportionate to this goal, and should not constitute a means of arbitrary discrimination;

    c. set out time limits within which requests for the use of healthcare in another Member State must be dealt with, taking into account the specific medical condition, the patient's degree of pain, the nature of the patient's disability, and the patient's ability to carry out a professional activity;

    d. enable patients accessing treatment in another Member State to access their medical records - subject to data protection provisions; this has language implications;

    e. provide information to patients who are going abroad for treatment (or coming to Wales) for treatment and the terms and conditions that apply (including how to seek redress if things go wrong) and details on access procedures and system of appeals (much of this is already required under case law); it also states the Commission may develop a standard Community format for a prior information form covering the above information;

    f. have national contact points responsible for providing information to patients on their entitlements to cross-border treatment and helping them seek appropriate redress in the event of harm; the Commission has proposed that it manage the network of national contact points, outline the type of data to be collected and the nature of the information to be provided to patients; this may be a burdensome requirement.

21. The Directive also identifies areas of potential co-operation:
    - EU-wide recognition of prescriptions;
    - European Reference Networks;
    - Data Collection required by the Directive;
    - E-health; and
    - Health Technology Assessment Network.

22. EU-wide recognition of prescriptions – there will be European Union-wide recognition of prescriptions, prohibiting restrictions on recognition of individual prescriptions unless they are "necessary and proportionate to safeguard human health and are non-discriminatory" or are due to "legitimate and justified doubts about the authenticity or content of an individual prescription; However, because of an earlier infraction case on these issues, some action has already been taken under *"the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008".* It is likely though that further action would be necessary if the Commissions proposals are adopted.

23. European Reference Networks - the Directive aims to facilitate the development of such networks, which are the subject of an existing pilot study and aim to share expertise amongst clinicians in the treatment of rare diseases.

24. Data Collection required by the Directive - the Directive would create requirements on Member States around data collection and sharing. Article 18 requires that statistical and other data is collected on cross-border healthcare, the care provided, the patients and providers, the cost and outcomes of the care; this may generate new requirements.

25. E-health – the Directive provides for the Commission to adopt specific measures to achieve interoperability of health information and communication systems whenever Members decide to adopt them.

26. Health Technology Assessment Network - the EU has proposed that Member states shall facilitate development and functioning of a network connecting their authorities or bodies responsible for health technology assessment.

27. In general, we have concerns about the possible implications of the proposals in relation to cooperation. This is because they appear to significantly encroach on Member States competence in a wide range of areas. In addition, there are many pilot programmes in these areas, through voluntary working between Member States, that are ongoing and therefore any action by the Commission would be premature.

28. Other Member States, we understand, have expressed similar concerns about the co-operation proposals.

Likely change in workload and patient flows

29. There are already arrangements in place for Welsh residents to secure treatment abroad, under various reciprocal arrangements.

30. At the current level of uncertainty about the final form of the Directive, it is difficult to forecast its precise effects. However, the Department of Health has undertaken an impact assessment on the likely changes in flows for England, and that is drawn on for next section.

31. Currently the scale of people travelling overseas for NHS treatment is low. We know that, for example, in 2007 approximately 550 travelled under the E112 under regulation 1408/71.

32. The Department of Health (DH), while it does not currently collect data on the numbers of people who exercise their rights under Article 49 and seek reimbursement for healthcare received in another Member State, believes the number to be fairly small, but growing as awareness grows. They also estimate (with strong caveats) that some 50,000 people per year travel to other European countries for medical reasons (from Passenger Survey data): the great majority paid for privately.

33. DH believe it very difficult to predict how many people may seek healthcare overseas as a result of the Directive and very little data exists on cross border healthcare. It is quite possible that there will be very low take up, at least in the few years after the Directive is finalised.

34. As an indicator of likely take-up, DH have noted that few people took advantage of pilots run in the South East of England that offered patients on waiting lists the opportunity to travel overseas for treatment, with the NHS meeting the cost. Patients were happy with the quality of treatment overseas and most found it a positive experience, but some experienced difficulties regarding travel, language barriers and resuming the care pathway on return to the UK. Other countries have also noted small numbers travelling.

35. As to people coming to the UK for treatment, the case law, and in time the Directive, will apply. The draft Directive does not allow home systems to discriminate against patients from other Member States. However, the draft Directive also states that nothing requires a system to accept a patient for planned treatment to the detriment of other patients with similar health needs.

36. In this context, providers in receiving Member States do not have to accept any patient from another Member State. Although this is only stated in the recitals to the Directive rather than within the articles. This would seem to be helpful in protecting limited capacity. On the other hand if a provider has accepted an overseas patient for treatment and there are two patients who have the same clinical need, the Member State of Treatment cannot discriminate against the overseas patient.

37. As people coming to the UK for treatment will need to pay the cost to the NHS of the treatment they receive, there is unlikely to be any significant cost to providers as a result of the Directive. Patients can already come to Wales from other EEA Member States for treatment under the case law or using the E112 route, so changes in this area should not be great.

Impact of these changes in systems and flows on the NHS

38. The changes in the two sections above will have an impact on NHS Wales. How significant will they be?

39. Current assessment is that the absolute numbers of patients who choose to travel is, and will continue to be, small. Evidence from the NHS on willingness to travel for treatment suggest that people prefer services close to home, and language and cultural issues may act to further dampen willingness to travel to Europe.

40. However, any significant flow may pose problems. The NHS is a collective system, where services are planned and financed on a population basis. If individuals choose to travel and take money out of the system, it will potentially undermine the system's ability to sustain services. There is a potential conflict between the interests of the individual and the interests of the population as a whole.

41. It is for this reason that the UK supports the continued maintenance of systems of prior authorisation and gate-keeping. However, even with these, it is clear that there could be a significant flow of funds away from the NHS. The Commission has also been clear that if this occurs, Member States would be within their rights to limit patient mobility through Prior Authorisation arrangements. The UK view is that this must be something that is available to Member States from the start, rather than when the system falls over; this is in line with earlier Court Judgements such as the Watts case.

42. It is also clear that the proposed arrangements would place a new administrative burden on the NHS. While some Member States have market-based health systems that clearly specify prices, entitlements and conditions around specific treatments. NHS style systems have been developed in a different way. The system deals with individuals and provides services based on their needs. This has in the past meant that the UK NHS has low administrative costs.

43. The Directive suggests that there will need to be a great deal of new information collected and available for anyone from abroad seeking treatment here. This will generate work and costs that otherwise might not be a priority for Wales. Technically case law already requires all Member States to have transparent arrangements for determining entitlements and clarity on the level of reimbursement based on health service costs. However this does not mean that Wales would be required to establish a list or "basket" of entitlements or have specific prices for all treatments.