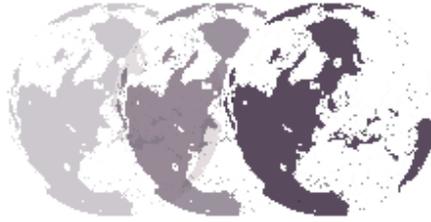


**The Centre for
International
Public Health Policy**



**Response to the Scottish Government's consultation on the
European Commission's proposals for a directive on the
application of patients' rights in cross-border healthcare**

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**Prof Allyson Pollock
David Price
Sarah Boesveld
Iain Law**

The Centre for International Public Health Policy makes the following submission under the Scottish Government's consultation on the European Commission's proposals for a Directive on the Application of Patients' rights in Cross-Border Healthcare, December 2008 (hereinafter the 'proposed patient mobility Directive')¹.

¹ NHS Scotland (2008) Consultation on the European Commission's proposals for a Directive on the Application of Patients' rights in Cross-Border Healthcare.

Conclusions and recommendation

The proposed patient mobility directive fundamentally affects the division of power in the European Union with respect to public health policy.

The proposed patient mobility directive:

- will require Scotland to change its policy on the use of commercial providers for NHS care;
- provides insufficient protection to planned, integrated health systems;
- provides for user charges, co-payments or top-up charges that are contrary to universal health care goals and Scottish health policy;
- provides a direct challenge to devolution under the Scotland Act, 1998;
- is not necessary to ensure patient mobility and represents a renewed attempt to bring health services under internal market rules;
- has the potential to increase the exposure of health systems to European competition law and to increase the role of markets in health services organisation.

We recommend that the Scottish Government:

- opposes the adoption of the proposed patient mobility directive;
- makes urgent representations to the UK Government with respect to the protection of Scotland's devolved authority for health services organization and delivery.

Background

Social security systems within the European Union have been coordinated since 1971 under Regulation 1408/71, as amended by Regulation (EC) No. 1992/2006. Regulation 1408/71 makes provision for member states to adopt measures for the coordination of social security rules that are necessary to provide freedom of movement for workers. Article 22 of the regulation provides for an absolute right for workers and their families to emergency care and a right to elective care subject to prior authorization².

These provisions are not intended to harmonize social security systems and Article 152 of the EC Treaty (introduced in 1992 as part of the Maastricht treaty) asserts that community actions on public health shall respect the subsidiarity principle according to which health systems are the responsibility of member states. It states that Community actions: "shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care."

The principle of subsidiarity came under pressure in a series of private actions heard by the European Court from 1998. In several cases it was successfully argued that Article 49 of the EC Treaty prohibits restrictions on the freedom to provide services within the EU³.

In 2004 an attempt was made by the Internal Market Directorate of the European Commission to include health care under draft legislation that would liberalize all services in the EU. The proposals of this draft 'Services Directive'⁴ were designed to increase the European Union's capacity to

² Sauter W (2008) The proposed patient mobility Directive and the reform of cross-border healthcare in the EU. TILEC Discussion Paper 2008-034, Tilburg University, p8.

³ Dawson D, Mountford L (2008) Health care services and the single European market OHE Briefing No. 44 September 2008. London: Office of Health Economics.

⁴ The so-called 'Bolkestein Directive', after Fritz Bolkestein, then DG Internal Market.

regulate health and social care within the framework of Article 49⁵. The Commission took the view that economic growth in the services sector was being impeded by too burdensome regulation and it called for limitations on the freedom of governments to impede the right of private firms to establish where they chose (one of the fundamental economic freedoms on which the European Union is based).

The inclusion of health and social care in the deregulation agenda constituted the first explicit statement by the Commission that it viewed these services as economic functions subject to trade rules not social functions⁶. It also reflected the Commission's vision of a European-wide market in health-care services.

The attempt to use internal market rules to liberalize health services proved to be extremely controversial. The Services Directive was eventually rejected by the European Parliament on the ground that it failed to take account of the publicly funded and planned nature of health services⁷.

The current situation and the proposed patient mobility directive

The proposed patient mobility directive presents health services reform within a renewed European social agenda: 'The health systems of the Community are a central component of Europe's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.'⁸

However, the proposal is another attempt to codify European Court judgments with respect to freedom of movement under Article 49, one of the liberalizing provisions of the EC Treaty. Under current arrangements, cross-border health care is covered by two provisions. First, freedom of movement for workers within the EU is underpinned by Regulation 1408/71 which provides for full reimbursement of emergency care and qualified⁹ access to elective care. Secondly, under European court case law EU citizens are entitled to qualified access to elective or planned care where there are unreasonable waits in an individual's state of origin.

The proposed directive sets out a legal framework for patients' access to health services in another EU Member State, thereby establishing access to cross-border care as a general principle. Under the framework the patient's state of origin retains the power to determine which services are included in the publicly funded 'health care basket'¹⁰ but must also set up a system for reimbursing patients who obtain treatment from the basket in another EU state. Reimbursement may not exceed the cost of equivalent care in the home state.

For countries such as Scotland that have adopted non-market policies in health services, the proposal is therefore of crucial concern.

Criticisms of the proposed patient mobility directive

⁵ Rowland D, Price D, Pollock A (2004) Implications of the draft European Union services directive for health care. *Lancet*; 364: 1200-2.

⁶ Dawson and Mountford.

⁷ Commission Communication of 2 July 2008, Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare presented by the Commission, COM(2008) 414 final, Explanatory Memorandum, paragraph 1.

⁸ Commission Communication of 2 July 2008, p22.

⁹ Access is conditional on prior authorization.

¹⁰ Commission Communication of 2 July 2008, Explanatory Memorandum.

1 If adopted, the proposed patient mobility directive will require Scotland to change its policy on the use of commercial providers for NHS care.

The proposed patient mobility directive establishes a legal framework according to which NHS funding may be channeled to commercial providers in other countries and sets out conditions for a charging code. Article 6.4 lays down a requirement for a mechanism for calculating costs 'based on objective, non-discriminatory criteria known in advance'.

The involvement of commercial providers in NHS-funded care is contrary to Scottish policy. In 2004, Scotland legislated to abolish English NHS market reforms and restore an integrated, publicly provided service¹¹. The Scottish Government is currently consulting on further non-market reforms on the ground that 'commercial organizations, driven by the financial interests of shareholders, [are not] compatible with [the Government's] public policy of a mutual NHS.'¹² The proposed patient mobility directive lays down a patient's right to cross-border care that cannot be limited to public provision.

Furthermore, the proposed directive will require certain market arrangements to be introduced to the Scottish system in order to facilitate billing. Under current arrangements, in the English NHS, patients from overseas are charged at the national tariff rate¹³ whereas in Scotland various bodies can determine the costs of care and there is no schedule of charges¹⁴. The Scottish arrangements are unlikely to satisfy the legal requirements in the proposed directive for 'objective, non-discriminatory [costing] criteria known in advance'¹⁵. There is therefore a probable legal requirement on Scotland to put in place an equivalent to the national tariff system, one of the building blocks of the market-orientated approach adopted by the English NHS.

Moreover, there is no agreed costing or accounting method in Europe for hospital care. Nor is there agreement on the costs that should be included in reimbursement calculations. Recent research for the Commission suggests agreement on costing is unlikely to be reached in the foreseeable future¹⁶. This will create difficulties for audit and accountability.

Thus the proposed directive will require the re-establishment of commercial structures in Scotland's hospital sector that run counter to adopted policy in Scotland. Reforms will be required irrespective of the volume of patient movement or the non-comparability of health system costs.

2 A power to require prior authorization of treatment abroad provides insufficient protection to planned, integrated health systems.

In 1998, the European Court, recognizing the need for governments to plan their health systems, included provision for prior authorization of cross-border treatment¹⁷. The intention behind this

¹¹ NHS (Scotland) Reform Act, 2004.

¹² Scottish Government consultation on changes to eligibility criteria for providers of primary medical services. December 2008. <http://www.scotland.gov.uk/consultations>.

¹³ NHS (2007) Implementing the overseas visitors hospital charging regulations. Guidance for NHS Trust hospitals in England. www.dh.gov.uk/paymentbyresults

¹⁴ 'It is for the body which is providing the service, whether hospital or family health service practitioner or clinic or in some cases NHS Boards, to determine an appropriate charge.'
<http://www.scotland.gov.uk/Publications/2008/03/14162503/2>

¹⁵ Commission Communication of 2 July 2008, Explanatory Memorandum.

¹⁶ Rosenmoller M, McKee, Baeten R (2006) Patient mobility in the European Union. Copenhagen: EU Observatory.

¹⁷ Dawson and Mountford. See European Court Case C-158/96 *Raymond Kohll v Union des caisses de maladie (Kohll)* ECR I-1931.

provision was to ensure that governments could protect the interests of a balanced medical and hospital service by refusing to pay for treatment abroad. The failed Services Directive of 2004 put health care on an equal footing with commercial services in general and omitted a requirement for prior authorization. The proposed patient mobility directive restores the approach adopted by the European court, once again providing for prior authorization as a concession to governments' need for health system planning¹⁸.

The utility of prior authorization is in question under the proposed patient mobility directive. The proposal puts the onus on member states to satisfy the court that prior authorization is necessary¹⁹. Article 9.3 of the proposed directive allows prior authorization to be imposed where, among other conditions, the outflow of patients would seriously undermine the financial balance or rational planning of the system. However, the authors of the Framework Communication accompanying the proposed directive suggest that member states will find it difficult to prove necessity to the Court. They state: 'the overall volume of cross-border healthcare will not have a major impact on health systems as a whole'²⁰. In the Commission's view, therefore, there is no case for refusing authorization and the Scottish Government should not regard prior authorization as an opt out from the proposed directive.

3 The proposed reimbursement system provides for user charges, co-payments or top-up charges that are contrary to universal health care goals and Scottish health policy.

Whilst the Commission states that reimbursement should respect principles of universality, access to quality care, equity and solidarity, it also allows for reimbursement below the full cost of treatment. Under the proposal, the only requirement is that reimbursement shall not be less than 'what would have been assumed had the same or similar treatment been provided' in the home territory²¹. This means that top-ups of publicly funded care must be allowed where full costs exceed reimbursement rates.

User charges are contrary to Scottish policy and highly contentious in the UK as a whole because they foster two-track health provision and unequal care. The proposed directive therefore institutes a system that undermines universal goals. It also fails to acknowledge incompatibility between policies of charging and universality.

4 The proposed directive provides a direct challenge to devolution under the Scotland Act, 1998, in the absence of direct representation or consultation.

Key principles of the proposed directive have been developed in the High Level Group on Health Care (HLG) formed by the European Commission in 2004 to develop proposals on cross-border health care purchasing and provision. The group, involving experts from all member states, was created to provide for a 'reflective process' following the failure of the 2004 Services Directive²².

From 2004-2008 the UK was represented on the HLG by up to three officials from the Department of Health in England, namely, the director of strategy and business development, the head of

¹⁸ Commission Communication of 2 July 2008, p17-8.

¹⁹ Sauter W (2008) The proposed patient mobility Directive, p8.

²⁰ European Commission (2008). A Community framework on the application of patients' rights in cross-border healthcare. Communication from the Commission COM(2008) 415 final.

²¹ Commission Communication of 2 July 2008, Explanatory Memorandum.

²² European Commission. Overview of High Level Group on Healthcare.

http://ec.europa.eu/health/ph_overview/co_operation/healthcare/high_level_hsmc_en.htm

international affairs, and the head of European affairs²³. The group's proposals cover cross-border healthcare purchasing and provision, health professionals, centres of reference, health technology assessment, information and e-health, health impact assessment and health systems, and patient safety.

Neither HLG minutes nor the impact assessment²⁴ accompanying the proposed directive include a reference to consultations with the Scottish government about the implications of the proposals for UK devolution or for countries opposed to health services liberalization. Nonetheless, the new provisions have implications for both and a key effect of the Scotland Act 1998, the devolution of health services policy, is being overturned by the EU.

5 There is no necessity for a new legal framework based on Article 49 of the EC Treaty.

The proposed patient mobility directive emphasizes internal market prohibitions on Article 49 freedom of movement in the EU by instituting a new legal framework for cross-border care and undermining the prospects of prior authorization²⁵. However, its basic function can be met without a new legal framework or reliance on Article 49. Only a few patients, primarily those seeking foreign private care, would be recognized by the proposed directive but neglected by Regulation 1408/71²⁶. The capacity to amend Regulation 1408/71 in order to cater for this group without recourse to internal market rules is not explored.

On the evidence provided, the proposed directive is unnecessary in order to ensure patient mobility and constitutes a renewed attempt to bring health services under internal market rules. With its inclusion of commercial providers and the requirement for an equivalent of the national tariff system, the proposal has the potential to increase the exposure of health systems to European competition law and to increase the role of markets in health services organisation²⁷. It should be rejected.

²³ European Commission. High Level Group on Healthcare. Minutes 2004-8.

http://ec.europa.eu/health/ph_overview/co_operation/healthcare/high_level_hsmc_en.htm

²⁴ European Commission (2008) Proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Summary of the impact assessment. Commission staff working document, COM(2008) 414 final. Impact assessment

²⁵ Sauter W (2008).

²⁶ European Social Insurance Forum (2008) Joint position paper of the European Social Insurance Platform. Brussels: ETIS.

²⁷ Dawson and Mountford.