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Guest Editorial

Avoiding another directive: the unstable politics of European Union cross-border health care law

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Abstract: The European Union's (EU) 2011 Directive on cross-border patient mobility codifies the right of any EU citizen to travel abroad for treatment and be reimbursed on the same terms as they would be at home. Governments hoped it would end the string of court cases that had reshaped EU health law but this article argues that it is likely to produce yet more judicial challenges. Patient mobility is an attractive idea with unclear definitions and divergent implementation. In many cases, providers, insurers and governments will not communicate and leave the patient with a bill – almost daring the patient to sue, and the courts to make more policy. Governments should try to prevent this by investing in coordination and alternative redress for patients who might otherwise sue.

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The 2011 European Union (EU) directive on cross-border patient mobility promised a stable, legally coherent framework that would allow patients, doctors and payers to understand their rights to international treatment. It promised 'legal stability', an end to the series of court cases that had destabilized European health care law (directive 2011/24/EU). It confirms and circumscribes what the courts have already declared: patients in the EU, Norway and Switzerland have a right to go abroad for treatment in most cases. A patient who goes abroad and purchases health care that is available at home must be reimbursed for the expenditure. The specific grounds for refusing to reimburse cross-border care do not include managerial convenience.

To make cross-border patient mobility work, the Directive includes provision for national information points that will help patients travel for treatment, and for exchange of information such as lists of qualified practitioners. It also tries

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to take advantage of patient mobility by constituting 'reference networks' of providers that will pool efforts in certain kinds of care, provisions for closer cooperation on the treatment of rare diseases, and some general directions in health IT and technology assessment. Member states have until 25 October 2013 to bring it into force. The success and stability of the EU cross-border patient mobility regime is a topic of potentially global interest, since the EU has the most regulated system for managing cross-border patient mobility, and its member states generally have universal health care systems with good quality. If the EU cannot create a stable and workable framework for cross-border patient mobility, the prospects for the rest of the world to do so seem poor indeed (Jarman and Truby, 2012).

Why the directive might not end the arguments

The Directive makes it clear, as the Court had long established, that patients have a qualified right to treatment abroad, and that governments and health systems have an obligation to facilitate that. Its goal was 'legal stability', the circumscription of legal conflict into areas defined by legislation. Given that member states have managed to adapt well (Greer and Jarman, 2012), and the Court is becoming less assertive (Hatzopoulos and Hervey, 2012), it might seem that we can relax – accept of patient mobility that, "It's a fact, and it sort of works" (McKee, 2012).

Policymakers cannot quite relax. Further action is necessary and possible that will allow policymakers to more completely manage legal risks to the solidarity and coherence of health care systems. Because the Directive makes an attractive right more visible, without ensuring good implementation, we can expect it to produce more challenges as patients and interest groups try to use their new right. Identifying gaps that patients or interest groups could use, and filling them, is a worthwhile investment.

Cross-border patient mobility is an attractive idea

The idea that patients have the right to enjoy their basket of benefits anywhere in the EU is attractive. But there is scope for confusion: Not only does the Directive afford states multiple grounds on which to require preauthorization for funded care. It extends the territory in which a patient may receive their entitlements, but does not create new rights to treatment (e.g. recital 13). A Lithuanian citizen can get treatment anywhere, but can only get the treatments that Lithuania finances, with reimbursement at Lithuanian tariffs; a UK citizen can get treatment anywhere but only if a General Practitioner referred for that treatment. That distinction might well be lost on members of the public who seek planned treatment abroad without preauthorization, and expect to see it reimbursed.

The idea of cross-border patient mobility is most attractive in the case of the 'rare diseases' and 'networks of reference' provisions of the Directive (Arts. 12 and 13). Rare diseases, in the Directive, affect fewer than five out of every

10,000 patients (a difficult enough definitional point). The Directive instructs the Commission to prepare proposals for 'networks of reference' that coordinate to facilitate care. Against this backdrop, what are the odds that patients or their families might seek experimental or expensive therapy abroad and expect to be reimbursed, or that patients' organizations, which can be quite effective and are often funded by pharmaceuticals and medical devices firms, will try to argue for new treatments? If the EU builds networks to facilitate care abroad for people with rare diseases, it should expect them to use it and take exception if they cannot have care available in the networks. EU law has not attracted interest groups who use it to batter their way into mainstream markets for health care provision (Greer and Rauscher, 2011), but it might well intrigue makers of medicines and devices who want to expand use of high-cost treatments and who will lobby, litigate and form patient groups to achieve that end.

Cross-border patient mobility is still a poorly defined right

Caveat emptor is a perfectly valid principle for purchasing anything, especially if one is voluntarily stepping out of one's home country's regulatory system. The Directive, though, places limits on the ability of states and health systems to leave border-crossing patients to their own devices. The legal risks to health systems (and providers and patients) come about because the limits of their responsibility are not clearly enough defined. The basic principles are easy to articulate: patients can go abroad for treatment without prior authorization from their home country and be reimbursed for any treatment to which they would be entitled at home, at the rate payable at home (if they have an emergency or prior authorization, their home country payers pay the full cost). States, payers and providers all have obligations to ease the administrative process, mostly in Articles 4 and 5. But who exactly solves problems? The Directive and the courts are clear that it should not be the patient, and the patient has a right to sue under EU law in member state courts if reimbursement does become a problem for the patient.

The problems that can arise are well known (Legido-Quigley *et al*., 2007; Wismar *et al*., 2011). For example, under the Directive a patient can seek care and return home with an invoice and an expectation of reimbursement at the tariff of the patient's home country. Whose job is it to make sure that the invoice is in an understandable language and uses codes that the patient's insurance fund, government or doctor, can recognize? What redress is there if it goes wrong? Who organizes continuing care or transmits records? Understandably, providers, payers and governments are all reluctant to take on the responsibilities. There is little or no reason to disrupt ordinary IT and administrative procedures for a few patients. Efforts to compensate with electronic health records are presently confined to pharmaceuticals (where there is a comparable language) and are not yet implemented in some countries. Outside islands of e-prescribing, many parts of

health systems are likely to deal with patients on a case by case basis, and there is no reason to expect them to be particularly coherent or consistent.

Divergent implementation will create problems for patients and opportunities for interest groups

There are multiple ways to define the right to planned cross-border health care without preauthorization in practice, but it is likely that countries will differ in their solutions. Legislation and implementation give flesh to the poorly defined right in EU law. A Directive is a kind of EU legislation that outlines rules. It must then be 'transposed', translated into domestic law by implementing states. Then it must be implemented, which means the health systems of the EU must adapt to the transposed legislation. Many studies of EU politics point out that much can happen, and go wrong, at those stages – from governments failing to transpose or implement (in which case the EU legislation, as interpreted by courts, is directly effective), to parts of governments inserting their own policy ideas into ostensibly simple transposing legislation (Falkner *et al*., 2005).

The first implication is that anybody interested in health care policy will find themselves watching, or joining, repeats of the battles just fought in Brussels and Strasbourg. The second implication is that there will be divergence between member states, and it will be concentrated in politically delicate areas – the issues that were too hard to resolve in this Directive. The Commission will be very aware of openings and ambiguities in the legislation (Martinsen, 2009), as will some interest groups, and they will be able to advocate for new actions in areas such as health IT and rare diseases.

A large-scale simulation of the implementation, conducted in Brussels by the European Health Management Association and the European Social Observatory, repeatedly found that member states, providers and insurers were going to implement in the way that gave them formal compliance with a minimum of disruption. All expected to solve problems 'pragmatically'. Providers showed no interest in disrupting existing procedures for single patients; insurers were reluctant to take on the responsibility of informing patients about quality; no group seemed interested in translating languages and accounting codes or thinking about redress (Jelfs and Baeten, 2012). The result is likely to be patients left with bills and potential legal claims when, for example, payers and providers have disputes about the definition, appropriateness or reimbursement level of a procedure. Conceptual clarity does not equal procedural coherence.

Legal risk, political risk and legislation

The result of these factors is risk. Legal and political risk is not identified by consulting health policymakers about their efforts to implement or discussing the coherence of any given bureaucratic approach; it is identified by thinking

like a lawyer with an aggrieved client or an interest group with a telegenic patient. Health policy history is full of single, unrepresentative, cases that legal and political systems turned into policy problems.

New law is legally risky – the usual result of new legislation is not stability but a new series of court cases, in European and domestic courts, filed by individuals, interest groups and the Commission (Kelemen, 2011). The existence of legislation makes potential cases clearer and patients more aware of rights and more willing to sue, while legislation makes courts more comfortable deciding the issue. Even if the Directive is clear that states have rights to limit mobility, the detail of the new EU law invites courts to interpret. The apparent existence of a right invites interest groups to incorporate cases into their pressures for policy change. That, in turn, reawakens member states' interest in more legal stability, which means more prescriptive legislation that makes it clearer what they should and should not do. Political studies of the EU find that this pattern holds in areas as diverse as mergers, disability rights and the regulation of stock markets (Kelemen, 2011); in an EU policy area as dominated by litigation as health care, it would be strange if it were not to apply.

The attractive new right is politically risky if it means mobilized patients can argue politically that their country is denying them care that the EU organized. To date, the slow progress of EU patient mobility law has reflected the insignificance of interest groups supporting liberalization, against the substantial groups of professionals, insurers and policymakers who are suspicious of medical travel (Greer, 2011). The risk now is that it attracts providers, patient groups, often with industry funding, who want to use it as part of a legal–political strategy to expand treatment options.

Avoiding another directive: reducing legal risk

It is tempting to dismiss patient mobility in the EU as a minor policy issue with legal stability from a new Directive and a calmer Court. Given that legal threats to health systems are possibly greater in the application of competition law (Mossialos and Lear, 2012), that much of the most problematic mobility is among professionals (Glinos, 2012) and that the health policy effects of Eurozone economic and fiscal policy dwarf the effects of many EU health policies, it might seem like the legal risk from patient mobility is ignorable, and stability relatively assured.

But there is still work to be done in implementation if there is to be legal stability in patient mobility. Cross-border patient mobility is an attractive but poorly defined right, enforced by the courts at the behest of, theoretically, any patient who encounters a problem. Given that catering to a small number of travelling patients is not a priority for most health managers and professionals, they are unlikely to coordinate well. Its implementation seems likely to leave patients with the burden of organizing and financing their care – which is not the

intent of the legislation and is an open invitation to them to challenge decisions. Policymakers who value legal stability and coherent health policy should try to reduce the extent of divergent implementation, clarify the right, and try to reduce the number of disaffected patients and interests who try to exploit the legal instability in the Directive.

First, they should pay close attention to transposition and implementation of the Directive should put a high value on consistency across borders, particularly with neighbors and with countries who routinely send or receive pensioners. The promise of rare diseases treatment is likely to attract the attention of active patients and carers who are very interested in cross-border treatment. Groups representing them might be disproportionately likely to be organized, dedicated, and likely to build litigation into a political strategy, if they are promised something that is not delivered. States should pay special attention to the rare diseases program and make sure it does not promise care it will not organize or finance.

Second, there is one specific problem that states can address in implementation. That is the risk that a single patient presents a good case under some part of the Directive that causes the new legal stability to unravel. Here, governments have a positive opportunity to address divergent implementation and bad patient experiences. The Directive is clear that it should not be up to patients to organize and finance their cross-border care. Inconsistent implementation that leaves patients with bills creates legal risk. Incorporating a system that addresses patient concerns and helps them might help to prevent disaffected patients starting legal cases by ensuring that there are actually pragmatic solutions to patients' problems. The 'national contact points' in the Directive (Art. 6) could be low-level information providers, set up in the spirit of minimal compliance by grudging bureaucracies, but they could also take on this task, offering cheaper and less politically complex redress than the courts. Resolving troublesome cases informally might be a good investment for states interested in reducing the odds of their turning into court cases with larger ramifications, and the national contact points offer a way to do it. Just as with medical error, apology and remedial action might be an effective way to reduce legal risk from aggrieved patients.

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