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Avoiding another directive: The unstable politics of EU cross-border healthcare law

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Unless governments make sure that cross-border health care works well from the patients' perspective by coordinating and developing redress mechanisms they risk legal challenges that will give rise to yet more EU health care law.

The EU's 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.

The European Union directive on cross border patient mobility of 9 March 2011 promised a coherent new EU health law: a stable, legally coherent framework that would allow patients, doctors and payers to understand their rights to international treatment (directive 2011/24/EU). It establishes what the courts have already declared: patients in the EU, Norway, and Switzerland have a right to go abroad for treatment, and neither their home country nor the country in which they seek treatment may discriminate against them. A patient who goes abroad and purchases health care that is available at home must be reimbursed for the expenditure. There are only limited grounds for refusing to reimburse cross-border care, and they must be clinical. They do not include budgetary limits or 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 to turn patient mobility into a benefit by constituting "reference networks" of providers that will pool efforts in certain kinds of care, and provisions for closer cooperation on the treatment of rare diseases and health IT. Member states have until 25 October 2013 to

bring it into force, and many of them are just starting their consultations on ways to turn the Directive into domestic legislation.

Why the Directive might not end legal contests

The Directive certainly makes it clear that patients have a right to treatment abroad, and that governments and health systems have an obligation to facilitate that. It is precisely because it makes that attractive new right visible, without ensuring good implementation, that we can expect it to produce more challenges in the courts, as patients try to use their new right.

The evidence base for this argument is, first, application of research on the role of law in European integration (1), second, reading of the Directive and secondary literature (2), and third, the report of a simulation of the Directive's implementation. (3).

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, and passage of legislation about it might increase interest in it. There is also scope for confusion: while the directive extends the territory in which a patient may receive their entitlements, it does not create new rights to treatment (recital 13). A Lithuanian citizen can get treatment anywhere, but can only get the treatments that Lithuania finances. That distinction might well be lost on members of the public who seek luxury or novel treatment abroad and expect to see it reimbursed.

The idea of cross order patient mobility is most attractive in the case of the "rare diseases" provisions of the Directive (Arts. 12 and 13). Rare diseases, in the directive, affect fewer than five out of every 10,000 patients. The Directive instructs the Commission to prepare proposals for "networks of reference" that will help get better care for these patients, wherever they might be. Against this backdrop, what are the odds that patients or their families might seek experimental or unproven therapy abroad and expect to be reimbursed?

Cross border patient mobility is still a poorly defined right

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, for that would be discrimination on the grounds of nationality.

For example, under the Directive a patient can seek care and return home with an invoice and an expectation that it be paid at the tariff of the patients 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 understand? Understandably, providers, payers, and governments are all reluctant to take on the task

of medical translation, and the more difficult task of translating between different schemes for coding procedures that are often encoded in complex IT systems. For any individual provider, there is little or no reason to disrupt ordinary administrative procedures for one patient, and it is not realistic to expect any given provider, insurer, or health manager to understand clinical coding from another system or invoices in a different language. 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 generous to patients who went abroad or to foreigners who turn up (3).

There are multiple ways to solve the problem, but what happens if they do not cohere across borders? The patient is left holding the bill. That is not friendly to the patient, and is an invitation to litigation by that patient or on behalf of the patient by the Commission. Member state courts have frequently ruled for the patients in the cases that they see, which creates legal instability for providers and governments (4).

Divergent implementation will cause problems for patients

Legislation and implementation give flesh to the poorly defined right in EU law. A Directive is a kind of EU legislation that sets a more or less specific and prescriptive set of rules. It must then be "transposed", translated into domestic law by member states (and some of the countries, notably Norway and Switzerland, that implement much EU legislation). Then it must be implemented, which means the different payers, providers, and governments of the EU must adapt to the requirements of the transposed legislation and the practicalities of ensuing patient behavior. Transposition and implementation are particularly important because it is in those stages that member states must resolve the problems that the EU institutions deemed too difficult.

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.

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, and expected to solve problems pragmatically (or not at all). 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. In general, no group seemed interested in bearing the costs of making cross-border care truly seamless (3). 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 or reimbursement level of a procedure.

Legal risk, political risk, and legislation

The result of these factors is a state of high legal risk. Legal 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.

History tells us that the usual result of new legislation is a new series of court cases, in European and domestic courts, filed by individuals, interest groups, and the Commission (5). The existence of legislation makes potential cases clearer and patients more aware of rights and more willing to sue, while the existence of law makes courts more comfortable with the issue. 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; compared to the courts, the EU legislative process starts to look welcoming and like a way to undo specific decisions. Political studies of the EU find that this pattern holds in areas as diverse as mergers, disability rights, and the regulation of stock markets (1); in an EU policy area as dominated by litigation as health care (6), it would be strange if it were not to apply.

Avoiding another directive: Reducing legal risk

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 with member state implementation. 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 in court. Member states that wish to reduce legal risk should try to reduce the extent of divergent implementation, and clarify the right:

- 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 and might be disproportionately likely to be organized, dedicated, and likely to litigate 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.
- The history of other EU policy areas and health care services policy suggest that these measures will not be enough. All it takes is one disaffected patient to allow courts to make new EU law. Professions, governments, and managers should continue to monitor EU law.
- Finally, governments have a positive opportunity to address divergent implementation and bad patient experiences by developing a system to ease patient experiences and reduce the odds that a patient is aggrieved. The Directive is clear that it should not be up to patients to organize and finance their crossborder care. It is the responsibility of providers, insurers, and governments. 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.

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