

12.viii.08

Officer In Charge,
Public Consultation on the Patient's Rights Directive,
Department of Health & Children,
Hawkins House,
Hawkins Street,
Dublin 2.

RE: PUBLIC CONSULTATION ON THE PATIENT'S RIGHTS DIRECTIVE.

Dear Sir / Madam,

Please find enclosed a copy of the Submission of the Irish Medical Organisation to the Department of Health & Children on the draft Directive on the Rights of Patients in Cross-Border Health Care.

The IMO represents medical doctors who work in the public service and who are committed to the delivery of the highest quality of patient care. The IMO believes that the directive must not reduce the rights of patients to high quality health care in Ireland for which they pay a significant portion of their taxes both direct and indirect.

The IMO is available for further consultation should this be required.

Yours faithfully,

Dr. Joseph Richardson
Head of International & Policy Units
jrichardson@imo.ie

OVERVIEW

The Irish Medical Organisation is a registered trade union and the professional, representative body for medical doctors working in Ireland. It represents over 50% of all doctors working in Ireland. In its mission statement the IMO commits itself to 'the development of a caring, efficient, and effective Health Service.'

STRUCTURE OF THE SUBMISSION

The directive will treat cross-border health care under the following seven headings.

1. Pre-authorisation and access,
2. Quality and safety,
3. Patients' rights,
4. Cross-border collaboration,
5. Healthcare baskets and tariffs,
6. Past impacts of cross-border healthcare,
7. Cross-border healthcare data.

The Irish Medical Organisation will structure its submission around these themes.

FUNDAMENTAL GUIDING PRINCIPLE.

Health services provided by publicly funds are services of general economic interest and therefore not to be regarded as a subject to market forces within the normal rules of supply, demand and competition. They are services which are designed to give citizens the rights to social and health care which are guaranteed under the laws of their respective states. The guiding principle of this directive must be the efficient provision of services within the national health systems of the Member States rather than the promotion of mobility of patients as a principle in itself. Where mobility adds to the efficiency of the national health services, it may be facilitated.

PRE-AUTHORISATION AND ACCESS.

The patient enjoys the right to automatic access to primary care without authorisation since 1971 under the 1408 Regulation on Social Services. The IMO welcomes the consolidation of this right within the new draft directive and agrees that the people travelling should be able to avail of primary and emergency care in all member states.

Problems may arise however if the right to automatic care is exercised in border areas without appropriate controls. There is a conflict of rights between the individual's right to automatic primary care and the state's right to manage the financial and other resources of its publicly funded health system. It is imperative that there should be controls exercised which allow the state to maximise the value and efficiency of the publicly funded health system.

The draft directive places the power to define what constitutes 'hospital care' to the European Commission. The proposed definition, treatment which requires the patient to stay overnight in a hospital, is very vague and will encourage in-patient procedures in favour of day patient work or day procedures. This does not represent a sufficiently flexible definition of hospital care. In recognition of this problem, the Commission has also given itself the power to list a series of therapeutic interventions which may be carried out in hospitals and which should qualify as hospital procedures but which do not require an overnight stay. Here again though there is a problem since the Commission which is retaining to power to make the determination of what is placed on this list.

It would be much more efficient if the member states acting bilaterally were to determine what constituted hospital care. This would allow effective planning and the maximisation of return for resources particularly in the border regions of the EU.

QUALITY AND SAFETY.

Quality and safety for patients are a crucial factor in determining the efficacy of health care. In the report *Building a Culture of Patient Safety* the authors highlight the deficit of information and power between the providers of health care and the patient. They suggest that there be annual reports of validated patient safety data. If patients are to exercise an informed choice regarding cross border health care then they will need comparable tables of data for all countries of the EU.

The report also highlights the need to inform employers both within Ireland and abroad of the safety record of health care professionals. The recent problems with adverse events in cancer screening illustrate the absolute need for reliable data on health care professionals and health care systems in the EU to be available, in a comprehensible form, to all citizens of the Union.

The member States must allocate significant funding to collect, collate, and publish the patient safety data if the Draft Directive is to be effective.

PATIENTS' RIGHTS.

The failure to include health care under the Services Directive was in no small measure due to the 'country-of-origin' principle which placed the patient at a disadvantage in vindicating his rights against a foreign health care provider. In the relevant sections of the Directive, Art. 5(d)(e) and Art. 11 the patient's right of redress is mentioned but the same disadvantage is maintained. These sections place the patient at a disadvantage in vindicating his rights in the case of an adverse event since the patient must sue the authorities in the state where the service was provided rather than through the courts of his own home state. The draft directive must be revised to make health care providers subject to the courts of any other member state in which they purport to provide health care. In the case of publicly funded health care providers, the Member States should conclude bi-lateral agreement which will facilitate the vindication of his rights by any patient.

CROSS-BORDER COLLABORATION.

The duty to collaborate across borders is commendable and should allow for the optimisation of health care resources in border areas. The BMW region has traditionally suffered from fragmented public services, the draft directive has the potential to offer a mechanism for enhanced co-operation. It goes without saying that the both jurisdictions in Ireland should retain the competency to agree collaboration and that the should be minimal direction from the Commission in Brussels.

HEALTHCARE BASKETS AND TARIFFS.

The impact on the Primary Care Reimbursement Service of the right to automatic primary healthcare in another jurisdiction could have an adverse effect on the management of the PCRS especially in BMW region. The Department of Health must retain the right to manage the finances of the PCRS effectively through the allocation of additional funding to cover the expenses which accrue due to the exercise of rights under the cross-border health care directive.

PAST IMPACTS OF CROSS-BORDER HEALTHCARE.

Ireland has benefited significantly from the high levels of cross-border co-operation within the medical profession. The activities of the various Royal and Irish Colleges in this regard are very well known. Irish patients have also benefited from tertiary services in the UK for rare and extremely complex medical conditions. These links should be enhanced by the action of the directive especially through the European Reference Networks.

CROSS-BORDER HEALTHCARE DATA.

The IMO has prepared a response to the consultation process on Health Information Bill initiated by the Department of Health and Children. It emphasises the issues of

1. Consent,
2. Control of Data,
3. Enforcing ethical, legal, and moral constraints,
4. Patient Safety,
5. Unique Patient Identifiers,
6. Patient Participation,
7. Consistency and Clarity,
8. Definition of Health Care Information,
9. Sensitive Information and Security.

The creation of transferable electronic patient records creates problems for patients, doctors, and state agencies. These problems are magnified when the transfer of data occurs across borders. Of the nine issues referred to above, the following of central importance for the patient.

CONSENT

Transfer of data offshore must not negate the patient's right to consent and to withdraw consent because of the imbalance of power between the patient while in a foreign jurisdiction and the entity to which the data has been transferred.

CONTROL OF DATA

Transfer of data abroad must not entail that the patient loses control of the data. Aggregated, anonymised data should be treated with care and managed according to a precautionary principle so that only those qualified and authorised may have access to it. It must be technically impossible to relate such aggregated data to the data subject or patient. Aggregators of data must have a duty to ensure this occurs.

ENFORCING ETHICAL, LEGAL, AND OTHER CONSTRAINTS.

The enforcement of legal and ethical constraints on the use of data becomes more difficult with the increase in the number of legal jurisdictions involved in handling it. In Scandinavia, for example, no distinction is made

between the possession of the patient's record and possession of the patient's data. The doctor or hospital therefore owns and controls the data. Irish patients own their data but not the doctor's record. The patient must retain control of his data at all times.

PATIENT SAFETY

The aggregation of data will lead, if properly used, to an increase patient safety due to the increased evidence-based medicine and health care. This must be encouraged within the constraints of

SENSITIVE INFORMATION AND SECURITY.

The transfer offshore of personal data related to notifiable diseases and other sensitive health data must be kept to a minimum for security reasons. Even when aggregated and anonymised, there must be adequate safeguards with an audit trail to protect the security of the patient and to enable remediation in the case of breach of security.

CONCLUSION

The European Union has recognised that the highest levels of health and the maintenance of health care represent a key driver of economic and social prosperity. Commissioner David Byrne published *Enabling Good Health For All – A Reflection Process for a New EU Health Strategy* in July 2004 on behalf of the EU. This report represents the recognition at the highest international levels that health drives prosperity.

Health is closely intertwined with economic growth ... Increasing life expectancy at birth by 10% will increase the economic growth rate by 0.35% a year ... Ill health is a heavy financial burden. 50% of the growth differential between rich and poor countries is due to ill-health and life expectancy. Health expenditure is, however, too often viewed as a short-term cost, not as a long-term investment, and is only now starting to gain recognition as a key driver of economic growth.¹

The publicly funded health care services represent a public investment in prosperity and a concrete expression of solidarity, two of the elements of the European Social Model. The draft directive must operate within the context of this model and not distort the efficient delivery of mass health care services in favour of a health care model driven by liberal economic doctrine with a net increase in cost to society.

¹ *Enabling Good Health For All – A Reflection Process for a New EU Health Strategy*, (July 2004) p.4