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Legal aspects of Health Data Cards (Patient and Professional)

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**LEGAL ASPECTS OF HEALTH DATA CARDS
(PATIENT AND PROFESSIONAL)**

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1. Context of the report

A large number of legal questions have been raised by the different working groups and justifies the fact that the present working group has amongst its different missions, an analysis of the legal framework for medical data cards.

This legal environment has to take into account the fact that the card might have different functions: the card can serve administrative purposes only or if it is a medical record, it can contain only « emergency » data or data related to specific diseases. The card can either be used as an interface with other data bases or be considered as an autonomous data base. As regards the holder of the card, one has to distinguish between the patient data cards and the health professional data cards.

Medical data cards are of interest to a certain number of persons. Each group has a specific interest:

- firstly, the users of the service, the parties to the basic transactions health care personnel (physicians, nurses, etc.) and patients;
- secondly, the providers of the service, those who issue the cards (industrial supplier, hospital, trust centers, social security administration, etc.);
- thirdly, persons peripheral to these relationships (laboratories, pharmacists, government authorities for statistical purposes, employers, etc.).

The role of the law is to organize the relationships between all these actors, taking into account the legitimate needs of each and the risks created by this new instrument.

2. Privacy Regulations

In the first place, we have to highlight the general principles of the privacy regulations enacted (most of the European countries and Quebec have a privacy regulation derived from Council of Europe Convention) or proposed (particularly the European Directive on Privacy) together with the ethics of professional secrecy sanctioned by criminal provisions in most of our countries.

In that context, the legal report will also have to take into account different texts, codes of behaviour or recommendations issued by the Council of Europe (e.g. the Council of Europe recommendation on automated data banks in the medical sector) or by national privacy authorities like the French Commission Nationale Informatique et Liberté or the Quebecian Privacy Commission.

Considering these regulations, the significance of certain concepts and of certain principles has to be highlighted. In particular, it is necessary to determine who owns the medical data card. The following principles have to be taken into account :

- Personal data have to be obtained and processed fairly (art. 5a of Council of Europe Convention n°108);
- Personal data must be stored for specific and legitimate purposes and not used in a way incompatible with those purposes (art. 5b Council of Europe Convention n°108);

- Personal data must be adequate, relevant and not excessive in relation to the purposes for which they are stored (art. 5c Council of Europe Convention, °108);
- Adequate security measures must be taken, provided the nature of the data stored and the risks occurred (art. 7 Council of Europe Convention, n°108).

Nevertheless, the consequences of all these regulations are important for the implementation and the use of medical data cards:

- The structure of the cards: the necessity of structuring the card in different zones of access in order to ensure selective and limited degrees of access must be established (e.g. distinction between administrative data, emergency data, other clinical data);
- As regards the delivery of the cards: complete information about the purpose, the nature of data stored, the categories of people authorized to read the content of the card, the means of access to this content by the holder is needed ;
- The content of the card: does the patient have the right to deny the inclusion of certain data or to request the erasure of data ?
- The use of the card: it must be clear that the physician, with or without the consent of the patient, is not allowed to use the card for purposes other than those in strict relations with the provision of continuity of health care. However, it should be understood that no individual can be forced to disclose the contents of the card and that no discrimination based on the non-presentation of the card can be established.

3. Professional secrecy

Data covered by professional secrecy must remain confidential if recorded by people bound by it and in conditions in which it is applied.

The rule of secrecy is to be found in all the European legislations. Three questions can be raised thereabout in the context of medical data cards:

1. It is generally admitted that the patient has a recognized right to information, although this right may be limited in certain cases, notably where knowledge of diagnosis could have a detrimental effect on the physical and mental health of the patient. Insofar as the patient data cards will provide to the patient an access to the entire records, these exceptions may be impossible;
2. The secret may be shared in the interest of the patient when ensuring the continuity of care. Professional data cards offer a way for sharing data. Thus it is necessary to specify the people authorized to have access and the legitimate functions for which they are authorized;
3. Finally, in certain cases, the divulgence of the medical secrecy is authorized by the law (e.g. vis à vis certain administrations or the Courts). So it may be interesting to see how the people authorized in these contexts may request the access to the patient data card's content.

4. Liability

The question of liability is also important to solve:

- firstly, the nature and liability of the « institutions » which deliver the cards, in omitting certain informations or in granting access rights to non-authorized people. On the last question, the role, and status of the trust center in charge of issuing and renewing the card has to be discussed.

What happens if there are different institutions delivering different cards ?

- secondly, the liability of health professional,
 - for failing to respect the patient's rights,
 - for entering false or wrong data, which might result in damage to patients,
 - for not updating the data on the card,
 - for giving access to unauthorized people.

It is obvious that this liability can be more easily proved, provided that all information entered on the cards be signed. In this context, the value of an electronic signature has to be discussed and also the evidential value of the printout of the content of the record kept by a professional card holder in order to prevent patient's arguments about the presence or absence on the card of certain data.

Another problem to be solved is the situation when it is acceptable for the patient to have the right to deny the entry of medical data or to request their withdrawal, as the reasons for doing this could be misunderstood. The fact that data contained in the card is false, incomplete or obsolete may perhaps exonerate a physician who has placed reliance on that information, from his responsibility. From an other point of view is, that it is his duty, within reasonable limits, to make the necessary investigation to verify the accuracy of data.

- Finally, it can be of interest to analyse the different ethical, criminal and civil punishments available in these cases.

5. Additional topics

The working group has to deal with the analysis of the legal value and the content of the existing documentation, and to manage these relationships. In rare cases, there is a contract between the actors, between the physicians delivering the card and the patient, between the trust center and the health professional. In other cases, there is a code of behaviour regulating the issuing and the use of the cards. A solution to be investigated would be to propose standard contracts in order to achieve a better protection of the users and to specify the duties and the responsibilities of each actor.

All the questions described above have to take into consideration the transnational characteristics of the use of data cards. Consequently, the problem of the law applicable and beyond that, the problem of discrepancies between legislations have to be addressed.