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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE IRELAND

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European Commission
Directorate General Information Society

Brussels

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1 Documents

1.1 Applicable Documents

[AD1]	Services Contract 30-CE-0162056/00-04

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/

	gp_survey_final_report.pdf, Country profiles: http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
[RD9]	Communication from the European Commission, "A Community framework on the application of patients' rights in cross-border healthcare", 2 July, 2008, http://ec.europa.eu/health-eu/doc/com2008415_en.pdf
[RD10]	Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, http://ec.europa.eu/health-eu/doc/com2008414_en.pdf
[RD11]	European Commission, IDABC, eID interoperability for public government services (with country profiles): http://ec.europa.eu/idabc/en/document/6484/5938
[RD12]	European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): http://ec.europa.eu/idabc/en/chapter/6000
[RD13]	Legally eHealth, Study on Legal and Regulatory Aspects of eHealth,http://www.ehma.org/projects/default.asp?NCID=140
[RD14]	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML
[RD15]	Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf
[RD16]	International Encyclopedia of Medical Law (editor: Herman Nys), http://www.ielaws.com/medical.htm, (with country monographs)

2 Glossary

2.1 Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- **Authorization:** refers to:
  - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
  - or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication**: information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **eHealth**: a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **Electronic health record**: a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature**: data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription**: a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC47, issued and transmitted electronically
- **Healthcare**: the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Health care embraces all the goods and services designed for people's health, including preventive, curative and palliative infections, whether directed to individuals or to populations.
- **Health professional**: a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on

the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

- **Identification**: using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier**: attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.
- **Identity management**: Identity management (ID management) is a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient**: any natural person who receives or wishes to receive health care in a Member State;
- **Patient summary**: subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;.
- **Registration**: process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine**: exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

2.2 Acronyms

CBSS	Crossroads Bank for Social Security
EHR	Electronic Health Record
eID	Electronic Identity
eIDM	Electronic Identity Management
GP	General Practitioner
HiT	Health in Transition

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OCSP ..... Online Certificate Status Protocol

PKI..... Public Key Infrastructure

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NRN..... National Register Number

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SIS..... Social (security) Information System

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SSCD ..... Secure Signature Creation Device

SSIN..... Social Security Identification Number

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TTP ..... Trusted Third Party

3 Introduction

3.1 General overview of the Irish healthcare system

The Irish healthcare system is operated through the Health Service Executive (HSE) which was established under the Health Act 2004 and came into operation in January 2005. Under the Health Act 2004, the objective of the HSE is to "use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public". The HSE replaced the existing regional service provision, which had take place through regional Health Boards, with a central organisation.

The HSE is responsible for the provision of services in hospitals and at community level. In this respect, the HSE is divided into three service delivery units. These are: Population Health, which has the function of protecting the health of the entire population; Primary, Community and Continuing Care (PCCC) which has the function of delivering health and social services in the community and other settings; National Hospitals Office (NHO) which has the function of providing acute hospital and ambulance services. Delivery of all three sets of services is organised through four administrative areas: HSE West, HSE South, HSE Dublin North East, and HSE Dublin Mid Leinster.

The Department of Health and Children is the Government Department with responsibility for setting policy for the provision of healthcare services and (together with the HSE and other interested parties) for strategic planning of healthcare services.

The Irish healthcare system is funded through taxation. All persons resident in Ireland are entitled to receive healthcare. Child health, maternity provision and emergency care is provided free of cost to all. In respect of other services, a Medical Card is available to specified categories of people. This card entitles holders to free hospital care, GP visits, dental services, optical services, aural services, prescription drugs and medical appliances. People who do not have a Medical Card are required to pay a fee for these healthcare services. A Medical Card is available to people in receipt of welfare payments, people on low incomes, all people aged 70 or over regardless of means and people with some long-term or severe illnesses.
In addition to the public healthcare system, an extensive private healthcare system operates in Ireland. A high proportion of Irish people have healthcare insurance which traditionally was provided by a state-backed, not-for-profit insurer, the Voluntary Health Insurance Board (VHI). Although there are some private hospitals, much of the private care provided has taken place through public hospitals: medical consultants were permitted to treat private patients in public hospitals. Recently, a number of changes have occurred. Competition has been introduced in the market through a number of new health insurance providers. In addition, moves are in progress to introduce new contracts for consultants which will restrict the amount of private practice which a consultant may engage in.

3.2 Use of ICT in the Irish healthcare sector

A report produced in 2006 for the RIDE project: Current European Practices in providing interoperability in eHealth domains: Survey of eHealth initiatives in IRELAND: http://www.srdc.metu.edu.tr/webpage/projects/ride/deliverables/RIDED.2.1.1%20-%20CurrentPracticesIreland-DERI.doc
provides some information on the use of ICT in the Irish healthcare sector. It notes that several technology related expert groups have been established to promote activities and initiatives in eHealth throughout the Irish healthcare sector such as the National General Practitioner Information Technology (GPIT) and the Health Level Seven (HL7) Ireland. These groups have collaborated in several initiatives, including the National HealthLink and HealthLinkOnline project initiatives, which aim to provide and implement a healthcare communications network with specific reference to primary care practitioners and acute hospitals throughout Ireland.
The RIDE report also notes that the Health Research Board (HRB) in Ireland is responsible for managing a number of National Health Information Systems. The information systems provide high quality information for the planning, monitoring, and evaluation of health services and are an invaluable source of information for further medical research in Ireland. Currently deployed information systems by the HRB include the Psychiatric Inpatient Reporting System (NPIRS), the Drug Treatment Reporting System (NDTRS), the Intellectual Disability Database (NIDD), and the Physical and Sensory Disability Database (NPSDD). The report also states that a National Computerized Infectious Disease Reporting System (CIDR) has been in place since 1971 to manage the surveillance and control of infectious human diseases in the Irish population. This system is used as a shared-national surveillance information system between several clinical laboratories, food and safety organisations, acute hospitals, and other health agencies throughout Ireland.
A 2007 report on the status of the use of ICT by general practitioners in Ireland has been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe" (Empirica):
http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
The following key findings are taken from the Irish country brief:

"Ireland can be regarded as an average eHealth performer in the EU27. In terms of infrastructure, Ireland scores slightly below the European average rates: 73% of the Irish GP practices use a computer and 65% of the GP practices dispose of an Internet connection. In Ireland, broadband connections have not yet arrived in force; they are used in only 44% of GP practices.

The results reached for the storage of electronic patient data are more or less in line with the European average storage pattern. At least one type of individual medical data is stored in 68% of GP practices. The storage of medical patient data is slightly more common than the storage of administrative patient data. 64% of the Irish GP practices store at least one type of administrative patient data.

A computer is available in the consultation room of 68% of the Irish GP practices. However, only slightly more than half of the GPs actually use the computer for consultation purposes
with the patients. This implies an "availability versus use gap" of around 12%. This gap can be found in most European countries, going up to 50% and more for some Member States.

In Ireland the electronic exchange of patient data is not yet common practice.

Not more than 4% of the Irish GPs exchange administrative patient data with other care providers. This compares to an average rate of 10% reached in the EU27. With 15% of the Irish GP practices that exchange administrative data with reimbursers, Ireland is in line with EU average. …

Only 2% of the Irish GP practices exchange medical data with other health care providers. Ireland thus positions itself below the EU27 average of 10%. … 40% of the Irish GP practices receive results from laboratories. This result corresponds to the average rate that can be found across the EU27 member states. Electronic exchange of prescriptions, commonly referred to as ePrescribing, is practiced by not even 1% of GP practices in Ireland."

With regard to electronic exchange of patient data, a Discussion paper released in June 2008 by the Department of Health provides some additional data with regard to the National HealthLink project, (referred to in the RIDE report above) which provides for the transmission of test results between a hospital and a patient's general practitioner. The Discussion paper notes that 529 general practices (working out at 1176 General Practitioners) are registered with HealthLink with 18 acute hospitals and other health agencies involved. The message types currently online are: Laboratory Results, Radiology Results, Death Notifications, Discharge Notifications, Discharge Summaries, A & E Attendance Notification, Waiting List Updates and Out Patient Appointment Updates.

3.3 National eHealth strategy

Information was one of the six frameworks for change identified in the policy document: Health Strategy *Quality and Fairness: A Health System for You* published in 2001. The importance of progressing the information framework received repeated emphasis in later reports such as the Deloitte and Touche report on *Value for Money in the Health Services,* the Primary Care Strategy *Primary Care: a New Direction* and the Brennan and Prospectus reports. A National Health Information Strategy (NHIS) was formulated and published in 2004 by the government to recommend the necessary actions to rectify previous and present deficiencies in the Irish health information systems and to put in place the frameworks to ensure the optimal development and utilisation of health information within the Irish health

system. The Health Information and Quality Authority (HIQA) was established with the brief of playing a key role in supporting the achievement of the necessary systems improvements. The National Health Information Strategy puts emphasis on the creation of a health information portal, the efficient adaptation of other health data formats and standardisation efforts, the development and implementation of a national Electronic Healthcare Record (EHR), the development of a unique person and patient identifier scheme for use within the health system, and the use of electronic cards for accessing healthcare records. The Strategy proposed the introduction of a Health Information Bill as helping to create a new and rigorous information governance framework.
A Discussion Paper on the proposed Health Information Bill was released in June 2008 which invites responses by September 11, 2008. The purpose of this Discussion Paper is to facilitate the preparation of the Health Information Bill by ensuring an informed consideration of the relevant issues. The Discussion Paper acknowledges that e-health solutions have the potential to make a major contribution to a range of issues faced by the Irish healthcare system such as: improved patient safety; more evidenced based care and seamless integrated care; greater financial efficiency in healthcare services; empowerment of patients; and improved planning, management and delivery of health services and health projects. The main purposes of the proposed Bill are set out as follows:

- to establish a legislative framework to enable information –in whatever form- to be used to best effect to enhance medical care and patient safety
- to facilitate the greater use of information technologies for better delivery of patient services, and
- to underpin an effective information governance structure for the health system generally.

Key e-health issues identified for consideration by the Discussion Paper include the rules which should accompany the introduction of a unique health identifier and the legal issues that need to be considered in establishing a national Electronic Health Records system.

3.4 Regulatory framework for patients' summaries

Ireland doesn't yet have legal provisions in the area of patients' summaries. In 2004, the National Health Information Strategy recommended the introduction of an electronic healthcare record on a phased basis. The Discussion Paper released in June 2008 seeks to stimulate informed consideration of the legal issues to be considered in establishing a National Health Records system.

3.5 Regulatory framework for telemedicine

There are no specific legal provisions in place Ireland with regard to telemedicine. On the other hand, there don't seem to be any major legal obstacles to the practice of telemedicine in

Ireland and indeed a number of initiatives have been undertaken in that regard.[1] The National Health Information Strategy (2004) recommended that HIQA develop a multi-annual information and ICT action plan which would set out national ICT priorities for *inter alia* "Telehealth solutions". The Discussion paper of June 2008 acknowledges the potential contribution of proper use of quality based information systems and modern communications technology (ICT) to extending the scope of healthcare beyond its current boundaries in areas such as "telemedicine which has particular relevance for rural and island communities". However it does not specifically invite submissions on the issue of the regulation of telemedicine.

3.6 Regulatory framework for electronic prescriptions

There is no regulatory framework for electronic prescriptions.

3.7 Overview of relevant legal framework

Of particular interest to eHealth are:

- the unenumerated constitutional right to privacy
- the laws on the protection of privacy in the contest of personal data protection: Data Protection Acts 1988 – 2003 (http://www.dataprotection.ie/documents/legal/Compendium_Acts.pdf) and

Also relevant are:

- The Freedom of Information Acts 1997 – 2003 (http://www.oic.irlgov.ie/en/FOIActsRegulations/TextoftheFOIActs19972003/).
- Laws relating to social security (in particular the provisions relating to the use of PPS (Personal Social Service) number (Social Welfare Consolidation Act Number 26/2005), s.223
- Electronic commerce law, in particular, the Electronic Commerce Act 2000 (Electronic Commerce Act, Number 27/2000) and the Electronic Commerce Regulations (European Communities (Directive 2000/31/Ec) Regulations S.I. No. 68/2003) which concern electronic documents, electronic signatures and admissibility of evidence in electronic form.
- the Health Act 2007 (http://www.bailii.org/ie/legis/num_act/2007/a2307.html) which establishes HIQA and conferred certain functions on it as per the National Heath Information Strategy

[1] MacFarlane, A., Murphy, A. and Clerkin, P., "Telemedicine services in the Republic of Ireland: An evolving policy context" Vol.76, Issue 3, May 2006, 245.

4 Regulatory Framework for Healthcare Professionals

The regulatory framework for healthcare professionals in Ireland has been extensively reformed in recent years. The primary regulatory instruments are the Health and Social Care Professionals Act 2005; the Medical Practitioners Act 2007 and the Pharmacy Act 2007.

4.1 Legal Conditions for the Practice of Healthcare

A person cannot practice medicine in Ireland unless he or she has been registered by the Medical Council. The Medical Council was established by the Medical Practitioners Act 1978; its composition and functions are now determined by the Medical Practitioners Act 2007.

The Medical Council must maintain a register of medical practitioners. This is divided into four sub-categories. First, there is a General Division which is open to any person who has completed medical training in Ireland, the EU or elsewhere and/or who has completed any required examinations and/or who has satisfactory evidence of experience. Secondly, there is a Specialist Division which is open to a person who has completed specialist training in a recognised medical speciality. Third, there is a Trainee Specialist division which is open to a person in an "individually numbered identifiable post which has been approved by the Council for the purpose of medical specialist training." Fourthly, there is a Visiting EEA Practitioners division which is open to practitioners who are lawfully established in medical practice in another EU member state and who intend to practice medicine in Ireland on a "temporary and occasional basis." Procedures and criteria for registration in respect of the divisions are established by the Medical Council.

Entry to other branches of the healthcare profession operates along broadly similar lines. For the nursing profession, including midwives, the relevant registry is operated by An Bord Altranais (the Nursing Board) which was established by the Nurses Act 1985. For dentists, the relevant registry is operated by the Dental Council established by the Dentists Act 1985. For opticians, the relevant body is the Opticians Board established by the Opticians Act 1956. For pharmacists, the relevant body is the Council of the Pharmaceutical Society of Ireland established by the Pharmacy Act 2007.

4.2 Control over the Practice of Medicine

Control over the practice of medicine lies in the first instance with the Medical Council. The Medical Council is responsible for certifying any institution that proposes to deliver medical education and training and for the maintenance of standards in this respect.

The Medical Council also has an obligation to ensure ongoing professional competence among its members. Under the Medical Practitioners Act 2007, the Medical Council must satisfy itself as to the "ongoing maintenance of professional competence of registered medical practitioners." It is obliged (within one year of the commencement of the 2007 Act) to establish one or more schemes for the delivery of this function.

The Medical Council also has the function of determining fitness to practice of practitioners and of imposing sanctions, including removal from the Register of Medical Practitioners, of practitioners who are deemed unfit to practice.

The Medical Council also issues practice guidelines for members. The current guide is the *Guide to Ethical Conduct and Behaviour* (6th Ed, 2004). This Guide sets out the ethical standards for the medical profession and compliance with the *Guide* is relevant in reaching determinations regarding fitness to practice.

4.3 Professional Liability

In addition to the sanctions imposed by the profession itself, described in 4.2, professional liability may be imposed by the law. Liability may be imposed under the criminal law, under the law of tort and under the law of contract.

Most instances of professional liability arise in the law of tort and relate to the tort of negligence. In order to establish negligence, a claimant must show, first, the existence of a duty of care; secondly, a breach of that duty; thirdly, that the breach of duty harmed the claimant and finally, that the harm in question was reasonably foreseeable.

As professionals, medical providers owe a duty of care to their patients. This duty arises in both contract and tort and failure to comply with the duty of care may result in an award of compensation to the injured party. In addition, in some circumstances, medical professionals may owe a duty of care in tort to persons who are not their patients. In such circumstances, the determination of the existence of a duty of care is dependent on the establishment of sufficient legal proximity; the foreseeability of the harm caused and the absence of any countervailing public policy argument.

In establishing a breach of the duty of care, the claimant must establish that the professional failed to comply with the established standard of care. The standard of care for medical professionals is determined in accordance with principles laid down by the Supreme Court in *Dunne* v *National Maternity Hospital* [1989] IR 91. In the words of Finlay CJ:

The true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is whether he has been proved to be guilty of such failure as no medical

practitioner of equal specialist or general status wand skill would be guilty of if acting with ordinary care.

The requirement that the harm be caused by the breach of the duty requires a claimant to show that "but for" the actions of the defendant, the harm which occurred would not have happened.

4.4 Professional Secrecy

Medical professionals owe a duty of confidentiality to their patients. This derives from a number of legal sources. In addition, the Medical Council's *Guide to Ethical Conduct and Behaviour* (6th Ed, 2004) states (para 16.1) that:

> Confidentiality is a time-honoured principle of medical ethics. It extends after death and is fundamental to the doctor/patient relationship. While the concern of relatives and close friends is understandable, the doctor must not disclose information to any person without the consent of the patient.

This is subject to four exceptions: these are: when order by a Judge in a Court of Law or by a Tribunal; when necessary to protect the interests of the patient; when necessary to protect the welfare of society; when necessary to safeguard the welfare of another individual or patient.

The legal basis for professional secrecy derives from the right of privacy recognised in the Irish Constitution and under Article 8 of the European Convention on Human Rights. In addition, the duty derives from the common law protection afforded to confidentiality. Regardless of its legal basis, the duty of confidentiality is not absolute. In broad terms, the exceptions to the legal duty of confidentiality would fall within the same general categories as those set out as exceptions to the ethical duty in the Medical Council's *Guide*.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Ireland has had a Data Protection Act protecting the individual with regard to automatic processing of personal data since 1988. The 1988 Act was been amended in 2003 in order to transpose the provisions of the European Directive 95/46/EC.
Generally speaking Irish data protection law is similar to the European directive. Subject to the exceptions referred to, there are strong similarities between the Irish law and the Directive with regard to:

- the definitions of the essential concepts: e.g. personal data, processing, controller, processor, (art. 2 of the Directive);
- the rules regarding data quality (art. 6 of the Directive). As required by the Directive, the Irish legislation contains specific provisions on the further processing of personal data for scientific, historical or statistical purposes; The Act uses the word “research” in place of “historical”.
- the criteria for making personal data processing legitimate (art. 7 of the Directive). The consent criterion in the Irish Act refers to mere “consent” rather than “unambiguous consent”. Also the Irish Act contains some additional criteria over and above those found in Art.7 e.g. processing necessary for the administration of justice.
- the criteria for making sensitive personal data processing legitimate (art.8 of the Directive). The criterion referring to medical issues allows for the processing of personal data “that is necessary for medical purposes and is undertaken by (I) a health professional, or (II) a person who in the circumstances owes a duty of confidentiality to the data subject that is equivalent to that which would exist if that person were a health professional”. Medical purposes is defined as including “the purpose of preventive medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services”. The exception for medical research is not found in the Directive.
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject’s rights (art. 12, 14 and 15 of the Directive) although the Irish legislation added a specific provision regarding access to health data: see below.
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive);

- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Irish Data Protection Commissioner can be obtained from http://www.dataprivacy.ie/
- liability for damages as a result of unlawful processing (art. 23 of the Directive);
- transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

The restrictions on processing set out in the Irish Data Protection Acts are subject to a wide range of exceptions, some of which are not expressly provided for in Article 13 of the Directive. Section 8 of the Act provides inter alia that any restrictions on the processing of personal data do not apply if the processing is:

- required urgently to prevent injury or other damage to the health of a person,
- required by or under any enactment,

5.2 Information and access rights of data subjects

Special provision is made with respect to requests for access to health data. Section 4(8) of the Data Protection Act 1988 enabled the Minister for Justice, Equality and Law Reform to modify, by regulation, the right of access conferred on individuals with respect to personal data relating to physical or mental health. Regulations giving effect to the modifications were introduced in 1989, the Data Protection (Access Modification) (Health) Regulations, S.I. No.82 of 1989. The regulations provide that personal data relating to physical or mental health shall not be supplied to the data subject "if it would be likely to cause serious harm to the physical or mental health of the data subject". Provision is made for the granting of access to an edited version of the health or social work information requested. The Access Modification Regulations impose a further general restriction on the disclosure of health data that applies in all cases of disclosure of such information, even where such disclosure would not be damaging to the data subject: where a data controller who is not a health professional holds such data, he shall not disclose or withhold such data from an individual to which it relates before consulting with "the appropriate health professional".

5.3 Other relevant rules regarding access to health records

Separate provision for access to records held by public bodies is to be found in the Freedom of Information Acts 1997 – 2003. Again, there are special provisions modifying the access rights of individuals to health records, in this case: "records of a medical or psychiatric nature". The FOI Act (s.28(3)) permits the head of a public body to refuse to grant an access request where, in the opinion of the head, "disclosure of the information concerned to the requester might be prejudicial to his or her physical or mental health". Provision is made for the release of records to which access has been denied, to "such health professional having expertise in relation to the subject matter of the record as the requester may specify". The implication of such release is that the health professional will then be able to indirectly release

the information to the requester. As in the case of the Data Protection Acts, provision is made in the FOI Act for the granting of access to an edited version of the health information requested.

6 Rights and Duties of Healthcare Providers and Patients

6.1 Scope of the Law

The law regarding the rights and duties of healthcare providers and patients derives from a number of sources. First, individual rights are protected by the fundamental rights provisions under the Irish Constitution. A number of constitutional articles are relevant in establishing the extent of the duty. Of particular relevance are Article 40.1 which provides for a right of equality and Article 40.3.1 which sets out the personal rights of the citizen. These rights are "unenumerated" (or unspecified) but a substantial body of constitutional jurisprudence has developed and it is clear that the rights protected by this Article include: the right to autonomy; the right to dignity; the right to bodily integrity; the right to privacy and the right to freedom from inhuman and degrading treatment. In respect of children, Article 42 is important. This article places primary responsibility for children with the parents of the child.

Ireland has incorporated the European Convention on Human Rights into domestic Irish law through the European Convention on Human Rights Act 2003. Rights protected under the Convention are directly enforceable in the Irish courts.

In addition, professionals' and patients' rights and duties derive from the law of contract and the law of tort.

6.2 Duty of the Patient to Cooperate

There is no established duty under Irish law which requires a patient to cooperate with treatment. The matter is not dealt with by statute and it is unlikely that a duty of care in tort would arise. However, a professional could argue contributory negligence if a patient brought an action for negligence and the patient could be shown to have failed to co-operate with treatment.

6.3 Right to Quality Care

Under the law of tort, a patient who is provided with care is entitled to care in accordance with an appropriate standard of care, set in accordance with the established principles in *Dunne* v *National Maternity Hospital* [1989] IR 91.

6.4 Right to Freedom of Choice

A patient has the right to choose his or her healthcare provider. The Medical Council *Guide* states that all patients have a right to a second opinion and a medical professional must either

initiate or facilitate a request for this and must provide relevant information for an appropriate referral.

6.5 Rights Relating to Information about the State of Health

Patients have a right to information about their state of health. The Medical Council *Guide* (para 3.3) states:

> A request for information from a patient always requires a positive response. In general, doctors should ensure that a patient and family members, subject to patient consent are as fully informed as possible about matters relating to an illness.

The right to information is also derived from the duty of care under the law of negligence. Failure to disclose material information may give rise to an action in negligence if the patient can establish harm was caused by the failure to disclose the information. For the main part, actions based on failure to disclose information have related to information in advance of surgery. In *Fitzpatrick* v *White* [2007] IESC 51, the Supreme Court held that the relevant test to determine what information should be conveyed in these circumstances was on the basis of what a reasonable patient would wish to know.

In addition to the underlying right to information, a patient has a right to have this information conveyed in a clear and comprehensible manner. The Medical Council *Guide* (para 3.3) states:

> Patients do not always fully understand the information and advice given to them by doctors. They should be encouraged to ask questions. These should be answered carefully in non-technical terms with or without information leaflets. The aim is to promote understanding and compliance with recommended therapy.

The courts have been less forthcoming in setting out a right to clear and comprehensible information; however, there are indications in the case law that such a right exists.

6.6 Right to Give Consent

All patients have a right to give and refuse consent. The Medical Council *Guide* (para 17.1):

> A competent adult patient has the right to refuse treatment. While the decision must be respected, the assessment of competence and the discussion on consent should be carried out in conjunction with a senior colleague.

The courts have confirmed the existence of the right to consent. The legal right to consent derives from the Irish Constitution and from the common law.

The right to consent is not absolute. The courts have noted that the right may be overridden. In *North Western Health Board* v *HW and CW* [2001] 3 IR 622, 748, Hardiman J noted that the right to consent to or refuse treatment could be overridden in "the case of infectious diseases," exceptions "based on social need", and exceptions "specifically identified by law."

6.7 Rights Related to the Patient's Medical Record

All patients have a right to a medical record. The Medical Council *Guide* (para 4.10) states:

> It is in the interests of both doctors and patients that accurate records are always kept. These should be retained for an adequate period (this may be for periods in excess of 21 years) and eventual disposal may be subject to advice from legal and insurance bodies.

In addition, patients have a right of access to their medical records. The Medical Council *Guide* (para 4.10) states:

> Patients are entitled to receive a copy of their own medical records, provided it does not put their health (or the health of others) at risk.

In addition, as noted above, patients have a statutory right of access to records arising under the Data Protection Acts 1988 and 2003 and under the Freedom of Information Act 1997. In addition to access rights, patients have a right to ensure the safety and security of their medical records. The Medical Council *Guide* (para 16.4) states:

> All medical records in whatever format and wherever kept, must be safeguarded. Doctors should take all reasonable measures to ensure that other health professionals and ancillary staff maintain confidentiality.

Security obligations also arise under the statutory frameworks referred to above. The Data Protection Acts 1988 and 2003 require that data be kept safe and that appropriate security measures must be taken to protect against unauthorised access to data.

6.8 Right to Protection of Privacy and Intimacy

All citizens have a right to protection of privacy arising under Article 40.3.1. The extent and ambit of this right is determined by the courts in individual cases. It has been established that the right to privacy extends to provide an entitlement to contraceptive treatment within marriage and reference was also made to the right of privacy in deciding to permit the withdrawal of life sustaining treatment from a woman who had been in a persistent vegetative state for 23 years.

6.9 Right to Representation in case of incompetence

Patients who lack competence may be admitted to wardship under the Lunacy Regulation (Ireland) Act 1871. If a person is designated a ward of court, he or she has a representative (known as a "committee") appointed. The representative may make some routine healthcare decisions. However, for more healthcare decisions, the authority of the court must be obtained. Judicial authority in this respect arises from the inherent *parens patriae* jurisdiction which allows the court to make decisions on behalf of a person lacking competence provided that the decision is made in the best interests of the person.

Irish law in respect of people lacking competence is expected to be reformed within a short time.

7 Identity management in the health sector

7.1 Overview

Ireland does not currently have a state issued ID card, and traditionally has never had a population register. There is no co-ordinated identity management system in place in Ireland. There is however a trend towards using the Personal Public Service (PPS) number as an identifier for access to government services, including in the healthcare sector. The PPS number is a mandatory unique identifier issued to all Irish nationals and to other individuals who have had reason to deal with the public services in Ireland. For Irish nationals, the number is now allocated on birth. All personal information relating to the PPS number is stored in a central authentic database (the Public Service Identity (PSI)), and is used in conjunction with the PPS number for authentication purposes.
Before 1979, there was no single unique identifier in use in the State. The creation of the Revenue and Social Insurance (RSI) number in 1979, and its subsequent development into the PPS number in 1998 has been the main focus for the horizontal integration of government services.

7.2 The PPS Number

Until 1998, the RSI number, as it then was known, was used primarily for the delivery of social welfare, and for tax collection. In 1997 and subsequent years the purposes for which the number could be used were broadened considerably. The first time the RSI number was put on a statutory basis was under Section 23 of the Social Welfare Act 1993, which gave the Minister for Social Welfare the power to issue a "personal social services number" and laid out the identification procedures required before a number be issued. The RSI number was renamed the Personal Public Service number by Part IV of the Social Welfare Act, 1998. The change in name marked a change in the use of the number, from being used only by the Revenue Commissioners and Department of Social Welfare, to being used by public services in general. The current legislative basis of the PPS number is to be found in s.223(2) of the Social Welfare (Consolidation) Act 2005, which provides that "the Minister may allocate and issue a personal public service number to each person who is the subject of a transaction with a specified body". A "specified body" originally consisted of the following: a) a Minister of the Government, b) a local authority, c) a health board, d) the Revenue Commissioners, e) an Foras Áiseanna Saothar, f) An Post, g) An tArdChláraitheoir, h) the Legal Aid Board, and i) An Garda Síochána and Defence forces for their own members.[2] However the concept of a "specified body" has been expanded every year since, except 2001. As a result, there exist many hundreds of "specified bodies". A complete list of all specified bodies can be found at

[2] Social Welfare (Consolidation) Act 1993, Section 223(1) as amended by the Social Welfare Act 1998, Section 14

the website of the Department of Social and Family Affairs at http://www.welfare.ie/topics/ppsn/cop.html#appbbodies. The list includes the Health Service Executive and voluntary hospitals.

According to the Department of Social and Family Affairs's website at http://www.welfare.ie/topics/ppsn/cop.html#appbbodies the following bodies operating in the health sector have adopted the PPS Number as a unique customer identifier:

- Health Service Executive
- General Medical Services (Payments) Board (GMSPB)
- Irish Cervical Screening and Breast-Check Programmes
- Department of Health Immunisation Programmes

The National Health Information Strategy (2004) notes that apart from exceptions such as these, client/patient identification systems tend to be unique within each agency or department in the primary and secondary care domains. To identify each person, basic demographic information is usually collected repeatedly at every client/patient contact with the health service. The Strategy proposed the formal adoption of a unique identifier for the health sector on the grounds that it would promote the quality and safety of client/patient care. The Strategy recommended that the PPS number be used as the unique identifier. It recommended the preparation by HIQA, in cooperation with the Departments of Health and Children and of Social and Family Affairs and various other agencies, of a plan for a unique identification system that meets the functional requirements of the sector and is based upon the PPS number and its supportive infrastructure. The introduction of a Health Information Bill to provide a framework for regulations and for the information dimensions of other health legislation was also recommended. According to the Department of Health's June 2008 Discussion paper on the proposed Health Information Bill, the Department of Finance is currently considering the development of a public service wide system for identity management purposes. The Discussion Paper states that: "This will see further consideration of the possible use of the PPSN or any other single identification number (SIN) across all of the public service. The case for and against an alternative sectoral based approach would also be considered." The Discussion Paper acknowledges that the Data Protection Commissioner has expressed concerns about the use of the PPS number as a Unique Health Identifier, in particular the Commissioner's concern of "the very real possibility that it could become a National Identification number by stealth…"[3][70] The Discussion Paper also notes that the Commissioner has made it clear that he has no difficulty with the introduction by the government of a unique health identity number – combined with sufficient safeguards - on the basis of properly debated and enacted stand-alone legislation.[4]

[3] Department of Health, *Discussion Paper on Proposed Health Information Bill*, 2008, p.41.

[4] *ibid.*

8 Electronic prescription

The Irish Medicines Board designates certain medicines prescription-only. In addition, other medicines may be designated as controlled medicines and these are subject to special additional constraints. The legal power to write prescriptions lies with a range of healthcare professionals; including medical practitioners, dentists, nurses and midwives. However, dentists and nurses/midwives are subject to more restrictions regarding the circumstances in which they may prescribe.

The primary source for the legal regulation of prescriptions is the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI 540/2003). Under Regulation 7, a prescription:

- Must be in ink and signed by the person issuing it with his or her usual signature and must be dated
- Except in the case of a "health prescription" (a prescription issues under the free healthcare provisions of the HSE), it must specify the address of the person issuing it
- Must clearly indicate the name of the person issuing it and state whether he or she is a medical practitioner or a registered dentist
- Specify the name and address and age, if under 12, of the person for whose treatment it is issued.

In addition, Regulation 17 prohibits the supply of the medicinal product from an automatic vending machine or by means of any other mechanically or electronically controlled device of a self-service nature. Regulation 19 prohibits the supply of any medicinal product by mail order. "Mail order" is defined as meaning "any supply made, after solicitation of custom by the supplier or by another person in the chain of supply whether inside or outside of the State, without the supplier and the customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and the order for supply."

9 General assessment

Ireland is not yet ready for full implementation of eHealth projects. In particular the absence of a unique identifier for patients and providers poses a significant barrier to the development of such projects. At present, the PPS number is being used as a unique health identifier in some healthcare contexts although the Data Protection Commissioner has expressed concern around its use for these purposes. In addition no legal framework is in place for electronic health records and summaries or for telemedicine or electronic prescriptions.
Some moves are being made towards addressing these issues. Consultation is underway with regard to the introduction of a Health Information Bill. The emphasis in the Discussion Paper on the proposed Bill is on the development of a regulatory framework for a unique health identifier and electronic health records. In this respect it is noteworthy that the Discussion Paper emphasises the importance of maintaining privacy, security, confidentiality and integrity of the information. The Discussion Paper does not directly address the issues of telemedicine or electronic prescriptions.

Irish data protection legislation follows closely the terminology of the Directive and does not pose any additional barriers to the development of cross-border eHealth services. The Data Protection Acts provide that any restrictions on the processing of personal data do not apply if the processing is required by or under any enactment thus leaving open the possibility of the overriding of data protection requirements by legislation mandating the processing of personal data in the eHealth context.

In terms of cross-border interoperability, this will depend in particular on how the issue of the unique health identifier is addressed. It is interesting to note that the Discussion Paper raises the possibility of the development of an identifier unique to the healthcare context as opposed to the use of a general identifier such as the PPS number in the healthcare setting.

Annex: Contact details of National Correspondents

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