Telemedicine and e-health

Report from a joint workshop
August 14 2002
Maastricht, The Netherlands

Scientific Committee of the 14th World Congress on
Medical Law and
Thematic Working Group 6 “Law and Ethics“
The Ehtel Association

Report compiled by
Leif Erik Nohr
Norwegian Centre for Telemedicine
## Contents

<table>
<thead>
<tr>
<th></th>
<th>Introduction</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Presentations</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2a</th>
<th>Taking e-health and telemedicine law forward in Europe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ben Stanberry, UK</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2b</th>
<th>Telemedicine and European Law</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stefaan Callens, Belgium</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2c</th>
<th>Legal aspects of health care over the internet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ellen Christiansen, Norway</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2d</th>
<th>Federal and state tensions in the regulation of e-health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nicholas Terry, USA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2e</th>
<th>New patient roles and new legal challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Leif Erik Nohr, Norway</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Comments and conclusions</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4</th>
<th>Appendix</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>16</td>
</tr>
</tbody>
</table>
Introduction

Dear reader

This document is the report from a workshop held on August 14 at the 14th World Congress on Medical Law in Maastricht, Netherlands. The Workshop was a joint effort between the Scientific Committee of the Congress and Thematic Working Group 6 (T6) “Law and Ethics” of the Ehtel Project. We would like to use this opportunity to thank the Scientific Committee who let us do this workshop, and a special thanks goes to our main contact in the committee, dr. Henriette Roscam Abbing. Furthermore, we will thank the presentators for their excellent contributions to the workshop.

The main purpose of this workshop was to draw attention to some of the legal matters we see as especially important at present and in the future. The intention of having this workshop at this Congress was to have the opportunity to introduce these issues before an audience of highly skilled medical lawyers and jurists of whom many possibly have not worked with legal aspects of telemedicine and e-health. Some 50 people attended the workshop, and it was our impression that the audience found the issues and presentations interesting.

In this report you will find collected the abstracts from all presentations given at the workshop. In the appendix, you will also find printed versions of the PowerPoint presentations. You will also find a chapter with some comments and conclusions based on the presentations and the questions and discussions that followed.

Tromso, Norway, October 8 2002

Leif Erik Nohr
Vice-chairman
Thematic Working Group 6
Ehtel Association
Presentations

2a

Taking e-health and telemedicine law forward in Europe
Ben Stanberry, UK

Curriculum Vitae

Benedict Stanberry, LLB (Hons), LLM (Wales), MRIN, CNI

Educated by the Salesian College in Hampshire and the American Institute for Foreign Study in New York, Ben has a Bachelor's and a Master's degree in law. He was an infantry officer in the Territorial Army and a temporary attaché with HM Diplomatic Service in West Africa prior to his appointment as a lecturer in maritime and commercial law at Cardiff University in 1996.

Ben left full-time employment with the University in 1998 (though he continued to be a Visiting Lecturer at Cardiff Law School until September 2001) and founded the Centre for Law Ethics and Risk in Telemedicine ("CLERT") which became Avienda Limited on 6 April 2001.

Ben is one of the foremost experts on the legal, professional, ethical and risk management aspects of telemedicine and ehealth. He is a frequent keynote speaker on these and related topics at both national and international events. He has published a wide variety of articles, papers and books on the subject and continues to be a frequent contributor to the literature in this field.
Ben is presently one of the eight members of the Board of Directors of the European Health Telematics Association (‘EHTEL’) and is the Acting Treasurer of the International Society for Telemedicine (‘ISfT’).

As Managing Director of Avienda Limited, Ben is responsible for the operations, finance and personnel side of the running of the business, one of Europe’s leading e-health and telemedicine consultancy firms. He is also one of the firm’s principle consultants.

Abstract

NA
Curriculum Vitae

Stefaan Callens gained a Master's Degree in Law at the K.U. Leuven (Belgium) in 1989. He took part in the Erasmus Programme and studied for one year (1988-1989) at the Université de Poitiers (France). In 1990, he attended Duke University (1990) in America, where he gained a Master's Degree in Law. In February 1995, he completed his doctorate at the K.U. Leuven with a thesis on medical data protection. He was subsequently appointed Professor of Health Law at the Faculty of Medicine of the K.U. Leuven.

Since 1995, he has been working as a lawyer at the bar of Brussels. He regularly publishes articles on medical confidentiality and data protection, medical liability, pharmaceutical law, genetics, bio-ethics, clinical trials, medical responsibility and hospital legislation. He is member of the review board of the Belgian Journal for Health Law and co-chairman of the bio-ethics session of the International Bar Association.

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Abstract

TELEMEDICINE AND EUROPEAN LAW

Stefaan Callens
Faculty of Medicine
KU Leuven, Belgium

Internet is increasingly used by patients to gather medical information. At the same time physicians can use the internet to inform patients on their practice or discuss with them the diagnosis, the treatment plan, the use of certain medicinal products etc. Services that are provided by a physician for remuneration (or financed) by electronic means at a distance and at the request of a patient do fall under the field of application of the recent European E-Commerce Directive.

The paper analyses the impact of this Directive on medicine. The Directive aims the approximation of national provisions regarding the establishment of service providers, commercial communications, electronic contracts, codes of conduct etc. The consequence of the so-called country-of-origin principle will be analysed in depth. The type of supervision as well as quality criteria that a country of origin might establish for online physicians will be discussed in the paper.
The paper deals also with two other issues that are important according to the E-Commerce Directive, i.e. the transparency principle of the online physician and the publicity issue. The Directive allows publicity by physicians under certain circumstances. It is expected that in view of this principle physicians will use internet to make publicity for their practice more than they did in the past. The paper will stress on the need to establish codes of conduct at Community level in order to determine which type of online commercial information is acceptable. The paper will provide some proposals to make sure that online publicity complies with the professional rules regarding the independence, dignity and honour of the profession, professional secrecy and fairness toward patients and other physicians.
Curriculum Vitae

Ellen K. Christiansen is a legal advisor at The Norwegian Centre for Telemedicine (NST) in Tromsø, Norway. She is working with telemedicine and health law in general, and is interested in health related websites and the health legislation in particular. For the time being, she is engaged in a project initiated by NST aimed at users and providers of health related websites on the internet (http://www.helse-vett.no). The target of the project is to offer guidance to both users and providers. Some of the articles are translated to English.

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Abstract

Health on the internet; some legal aspects

The number of Health Related Websites on the internet is increasing. They offer a wide range of different health related services with different names; guidance, information, counselling, health services, health related services, health websites among others. Some of them might be considered as “health care” as such.

There is no separate health legislation for Health Related Websites. This implies that if health care professionals provide health care via the internet, they are obliged to do so according to the general health legislation in force. Besides, everybody who processes health information has to do so in accordance with the acts relating to the processing of personal data. (In Norway: The Personal Data Act and the Personal Health Data Filing System Act.)

“Health care” is defined as:

“Every action which has preventive, diagnostic, treating, health preservative or rehabilitating aim and is conducted by health professionals.” (Unauthorized translation)

(Norwegian Health Personnel Act, section 3.)

This is a wide definition, and is referring to the aim or purpose of an action. The Norwegian Board of Health has stated that health advice based on health information from individuals, is to be considered as health care, whether advice is given via internet or in a face to face consultation. Prescribing, health certificates and referrals are to be considered as health care as well.

Patients’ rights correspond with health personnel’s duties according to the Health Personnel Act. When individuals receive health care via internet, from health
professionals inside or outside the public health care system, they will have certain patients' rights. The question is which they are and how these rights are to be taken care of in practice?

How can health personnel conduct health care via the internet “in accordance with the requirements to professional responsibility and diligent care” that is expected according to the Health Personnel Act, section 4?

These questions, among others, will represent great challenges to health authorities, patients/users of health related websites and providers of health related services in the future. This presentation addresses some of the main challenges and will suggest some possible ways to deal with them in the future.
Federal and state tensions in the regulation of e-health
Nicholas Terry, USA

Curriculum Vitae

Nicolas Terry (terry@slu.edu) is Professor of Law and Co-Director, Center for Health Law Studies, Saint Louis University School of Law. His teaching and scholarly writings concentrate on health law, professional negligence and e-commerce. His recent publications on the eHealth have appeared in the American Journal of Law & Medicine, the British Medical Journal, msJAMA, and the Journal of Medical Internet Research. Links to many of his publications may be found at http://law.slu.edu/nicolasterry/Resume.htm

Email: terry@slu.edu

Abstract

Federal and State Tensions in the Regulation of eHealth
Professor Nicolas P. Terry

Three issues dominate the legal and policy analysis of technologically-mediated health care; cross-border medical and pharmacy practice, the quality of health information publicly available on health-related web sites and the privacy and security of medical records. On both sides of the Atlantic federal and state authorities have reacted to these issues with discernible policies seeking to leverage health care technology to provide a greater range of interstate and intrastate services, reduce costs and reach underserved populations, while also increasing the level of protection for medical records by raising privacy and security standards.

In recent years, telemedicine in the United States has developed in an apparently positive legal environment. Reimbursement has increased and doctors involved in traditional telemedical scenarios have not faced substantial hindrance from state licensure laws (medical practice acts that generally prohibit cross-border practice). As the privacy of medical records has become a major regulatory agenda, strong federal standards for the "Privacy of Individually Identifiable Health Information" (PIHI) made under the Health Insurance Portability and Accountability Act 1996 (HIPAA) have emerged. The federal, uniform nature of these has further encouraged telemedical practice across state borders.

Increasingly, this positive picture of US telemedicine is being undermined by regulatory weaknesses displayed at the federal level and the passage of state laws that, while aimed at non-traditional telemedicine and Internet prescribing, nevertheless threaten responsible interstate and intrastate technologically-mediated practice.

First, state legislatures increasingly are adding new “telemedicine” provisions to their medical practice acts, the licensure and disciplinary mechanisms with which they
regulate physicians and pharmacists. These provision extend the definition of the “practice of medicine” to include technologically-mediated care received in the regulating state, add additional requirements such as record-keeping and informed consent, and discipline physicians involved in prescribing in the absence of a face-to-face consultation. In the absence of federal licensure and limited reciprocity, these regulatory systems raise protectionist issues and, more practically, suggest state policies that, while aimed at irresponsible and possibly unlawful behavior, may also endanger the practice of more traditional interstate and intrastate practice, possibly chilling responsible interstate or even intrastate practice.

Second, the Bush administration has repealed or softened several key provisions in the Federal PIHI regulations, specifically the requirement that a health care provider initially obtain the consent of the patient prior to the use or disclosure of identifiable health information for treatment and payment purposes. The PIHI regulations are subject to a “co-operative” preemption rule, such that state laws that provide for “more stringent” protection of patient privacy will not be preempted. With this decline in the protection at the federal level, fragmented state laws with various levels of protections potentially will frustrate providers interested in providing cross-border care.
New patient roles and new legal challenges
Leif Erik Nohr, Norway

Abstract

New Patients’ Roles and new Legal Challenges

Leif Erik Nohr, legal adviser, Norwegian Centre for Telemedicine, Tromso, Norway

According to OECD studies, the percentage of Gross Domestic Product spent on healthcare, nearly doubled between 1960 and 1997 in their 29 member states. In 1997, the states spent on average 7.6% of their GDP on healthcare. In the US the same percentage were as high as 13.6.

In this growing health care system, the patients are taking a more and more active role as true consumers. As consumers, they are impatient and demanding. They have big expectations about what the health care providers should provide, and they demand things like easy access, information, involvement and above all – quality. In their report “Health Cast 2010, Smaller World, Bigger Expectations”, PriceWaterhouseCoopers makes this statement: “Consumers will be the key customer group of the 21st century in healthcare. Beware providers and health insurers. Tomorrow’s consumers may be adversarial, fickle and decidedly impatient.”

Other forces that are driving this process is the development and focus on patients’ rights. Many countries have passed patients’ rights acts, and with that equipping patients with powerful tools as they enter the health care system. Furthermore, the development of modern information and communication technologies can be tools for patient empowerment. Patients seek information and advice on their conditions from the internet, they want to be able to contact their doctor via email, they want to have access to their own health records, etc. In addition, telemedicine and ehealth push forward a globalisation trend in healthcare. Patients can seek advice and treatment from the best doctors, regardless of where in the world the doctor may reside.

Consumerism and globalisation are not only trends that are a challenge to providers and health insurers. These processes will also represent a challenge to the legal framework that surrounds the health care systems. It will be a challenge to legislators, courts, lawyers and the lay patient-citizen. This presentation will address some of these challenges as we see them today, and will share some thoughts on what legislative
solutions one might choose in order to meet these challenges.
Comments and conclusions

Summing up

Someone once used an onion as a picture of what it is like to work with legal issues in the field of telemedicine; the more you peel the more layers you reveal. And this field is no longer just about new technologies and new applications introduced to health care. Internationalisation, globalisation, consumerism, patient empowerment and the use of internet are all strong forces that represents challenges and changes to the way health care is provided and consequently, legal systems and regulations are challenged.

Furthermore, it is important to be aware of that these are no longer just issues of academic interest. Telemedicine applications is being implemented in more and more hospitals and at more and more practitioners offices. The citizen-patient is getting access to a vast amount of health related information via the internet, and the big companies, being it soft- or hardware producers, pharmaceutical companies or consultants are spending big money on products and services in this new and expanding field.

Protection or barrier?

Several of the presentations pointed out the tension that exists between traditional legal regimes and regulations and the way these in fact can represent massive legal barriers for widespread use of telemedicine an e-health applications. Prof. Terry showed the differences at this point between the state and the federal levels in the US, and similar problems arise within different European legislations.

One issue is that state or national legislation represents hindrances for real cross border practicing of telemedicine. Traditional legal frameworks are established as a means to protect professions and institutions within each state, a notion that is seriously challenged by the possibility to use modern IC Technology to provide health care to patients wherever they reside. Current licensure legislation might in fact appear to be protectionist.

The danger of protectionism is even more apparent when it comes to allowing pharmacies to sell goods across national borders.

On the other hand, one should not forget the fact that national or state regulation is also considered a framework for protecting the citizen-patient. And state regulations aims at ensuring quality of the national health care system. An important question is what kind of protection patients can and should expect as forces of consumerism and globalisation reduces the power of national legal protection and leaves the citizen-patient with more responsibility for her or his health and treatment. Furthermore: What will happen to patients’ rights under a new legal regime?
These are major issues. These are issues that call for massive collaboration over national borders, both at a regional level and globally. The establishment of an organisation like The European Health Telematics Association means bringing together people and organisations that can identify issues like these and start working on solutions.

The Internet, challenges and possibilities

Both this workshop and a previous round-table session and several other presentations at the Congress dealt with the many legal challenges of doctors and patients providing and receiving care and advice on the internet. Many of the problems and issues mentioned in the paragraphs above do of course apply on internet practices, but in addition, there are several new and unsolved aspects.

In her presentation, Ms. Christiansen pointed out to what extent existing legislation applies to practicing telemedicine via the internet and some of the specific challenges this practice leads to. One distinction that is very important to make, is whether or not a service is indeed providing health care or just providing advice to citizen-patients. The distinction is important when deciding if a service and its providers are subject to the requirements of existing legislation or not.

Prof. Callens discussed the use of the E-Commerce Directive on medicine, showing that the directive applies to the use of e-health services under certain conditions. His presentation emphasised the importance of actually assessing existing legislation and the impact it may have on services in use today and in the future.

The use of The Internet also gives new possibilities both to providers and citizen-patients. At the workshop it was mentioned by several that The Internet is a powerful tool in terms of gathering and disseminating all kinds of health information. This, in its turn, contributes to the empowerment of patients and the strengthening of their position in the health care system. With regards to health care websites, it is at the same time important to be aware that the quality of the information varies a lot. This makes it important both to educate the users, to make them critical, and to find ways to ensure quality of the information and the way it is provided.

Conclusion

This workshop covered only a small fraction of the multitude of legal issues and aspects that emerges from the use of e-health and telemedicine. We think, however, that the workshop covered some of the more important issues. The number of people in the audience and the response we got during and after the event shows that there is an increasing interest in this field, also from people that are not working specifically with these issues.
Appendixes

Presentations

This appendix contains the Microsoft Power Point slides for each presentation at the workshop. The presentations are published here with kind permission from the presenters.

Do not use or copy from the presentations without author’s permission.
Taking e-health and telemedicine law forward in Europe

Ben Stanberry, UK

What is eHealth and Telemedicine?

“**eHealth**” — any aspect of clinical care or health services management that can be delivered by a computer, such as:

- electronic patient records
- computerised systems in healthcare (e.g., for booking patient appointments or ordering medical supplies)
- email and the Internet for communication between Health professionals and their patients and to provide information and services to patients or their carers
- Internet use in administrative and logistical tasks involved in modern healthcare systems such as supply purchasing and prescribing medications

What is eHealth and Telemedicine?

“**Telemedicine**”

- rapid access to shared and remote medical expertise by means of telecommunications and information technologies, no matter where the patient or the relevant information is located.
- the use of remote medical expertise at the point of need
- The essence of telemedicine is the exchange of information at a distance, whether that information is audio, an image, elements of a medical record, or commands for a surgical robot. It seems reasonable to think of telemedicine as the remote communication of information to facilitate clinical care

What is eHealth and Telemedicine?

“**Health Telematics**”

The application of information and communications technologies, usually in direct combination, to meet the specific needs of healthcare

Societies & Associations

- UK eHealth Association
- American Telemedicine Association
- European Health Telematics Association
- International Society for Telemedicine
- International eHealth Association
Societies & Associations

UK eHealth Association
American Telemedicine Association
European Health Telematics Association
International Society for Telemedicine
International eHealth Association

European Health Telematics Association
• Begun as a 2-year project funded by the European Commission in 1998
• EHTEL is a non-profit international, member association gathering actors involved in all sectors of the healthcare field with the aim of promoting the use of telematics solutions in healthcare.
• Members interact in various working groups, either with their counterparts in other countries or regions ("Actor Working Groups") or with others interested in particular issues ("Thematic Working Groups").

• The forum remains neutral, enabling all actors from the healthcare field to develop together concrete approaches to the implementation of health telematics.

Current members are healthcare authorities, healthcare providers, healthcare insurers, research institutions, standardization bodies, patient/clinician/consumer associations, industry groups and individuals predominantly from the European continent.

• The working groups enable a network from which consensus and policy building is possible, and provide a source of shared information and experience. The working groups also lead particular studies and analyses of various issues dealing with the implementation of health telematics.

• EHTEL also publishes a monthly newsletter, "The Navigator", and supports such initiatives as Best Practices through its website. The official languages of the association are English and French.

What is T6?
• "T6" is Thematic Working Group 6 of the European Health Telematics Association – the working group on law and ethics in health telematics.

• T6 received a mandate from EHTEL to carry out work in this field for the benefit of its members.

Standing Committee
• Dr. Kevin Dalton, Consultant in Obstetrics & Gynaecology and Legal Medicine, Addenbrooke’s Hospital and Fellow of St. Catherine’s College, Cambridge, UK.
• Dr. Christian Dierks, Lawyer, Messrs Dierks & Bohle, Berlin, Germany.
• Rina Hakimian, Senior Researcher, Gertner Institute for Epidemiology and Health Policy Research, Unit for Ethics and Health Rights, Sheba Medical Center, Tel Hashomer, Israel.
Legal Advisory Panel

- Dr. Zoi Kardasiadou, Independent Legal Consultant and Researcher at the Centre for International and European Economic Law, Thessaloniki, Greece.
- Joseph P. McMenamin, Attorney-at-Law, Messrs McGuireWoods LLP, Richmond, Virginia, USA.
- Leif Erik Nohr (Vice Chairman), Legal Adviser, National Centre of Telemedicine, University Hospital of Tromsø, Norway.
- Ellen Christiansen, Legal Adviser, National Centre of Telemedicine, University Hospital of Tromsø, Norway.

- Dr. Sjaak Nouwt, Center for Law Public Administration and Informatization, Tilburg University, The Netherlands.
- Prof. Stefaan Callens, Professor of Law, Principal, Callens Advocatenkantoor, Belgium.
- Benedict Stanberry (Chairman), Managing Director, Avenida Limited, Cardiff, Wales, UK.
- Dr. Petra Wilson (EC Observer), Brussels, Belgium.

The Challenge for T6

- Many keen EHTEL members but very few lawyers, jurists or ethicists
- Needed to acquire expertise and enthusiasm
- Still require national experts from many European countries
- The work is paid!

The Solution

- To research, edit and publish a “Green Paper” on the legal and ethical aspects of health telematics

Why A Green Paper?

- Need to consult all parties concerned
- Calibrate and quantify what the issues are and which issues present the most real and immediate problems
Why A Green Paper?

• Essential to "draw a line" under some existing research / writing and create proper evidence-base for future work

• Work must be transparent and effective

The Follow-Up (1)

• White Paper "Breaking Down Barriers" published in January 2002

• Programme of work for 2002 – 2003 includes:
  - Workshop and Publication on "Legal aspects of standardisation in health telematics"
  - Workshop and Publication on "Reimbursement and responsibility in health telematics"
  - Workshop on "Legal and ethical aspects of eHealth and Telemedicine"
  - Workshop on "Internet Pharmacies and Electronic Prescribing"

The Follow-Up (2)

• In 2003:
  - Workshop and Publication on "Privacy and Security of Healthcare Information"
  - European Conference on "Privacy and Security of Healthcare Information"

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For more information:

http://www.ehtel.org

Please leave your business card / e-mail address if you would like a copy of the proceedings of this workshop
Telemedicine and European Law
Stefaan Callens, Belgium

Content
- Need for a Legal Framework
- E-Commerce Directive
- Data Protection Directive
- Social Security Law
- Conclusions

Impact of E-Commerce Directive
- Aim
- Scope
- No Prior Authorization for the taking up of an Information Society Service
- Transparency

Data Protection Directive and Telemedicine
- Problem
- Transfer of data
- Need to obtain consent?
- Websites and data protection
- Research and data protection

Social Security Laws and Telemedicine
- Reimbursement
  - physical presence rule
- Compliance with Community Law?

Impact of E-Commerce Directive
- Need to have Community Codes of Conduct
  - commercial communication
  - quality of information
  - communication by e-mail between physician and patient

Telemedicine and European Law
Stefaan Callens
Professor of health law
Lawyer at the Brussels bar
www.callens-law.be
Conclusions

- Telemedicine is growing
- Legal framework is needed
Legal Aspects of health care over the internet
Ellen Christiansen, Norway

Health on the internet; Some legal aspects
Ellen K. Christiansen
Legal advisor
Norwegian Centre for Telemedicine
Ellen.Christiansen@telemed.no

Health related web-sites:
“A pet child has many names”
• Guidance
• Information
• Counselling
• Health services
• Health-related services
• Health web sites
• Health care
  The name is not decisive...

There is no separate legislation for health related web sites

“Health care”:
“Every action which has preventive, diagnostic, treating, health preservative or rehabilitating aim and is conducted by health professionals.”
(my translation)

It is important to distinguish between “patients” and “users”

Patient’s rights:
• Right to health care
• Right to participation and information
• Consent to health care
• Right of access to medical records
• Second opinion
• Special rights for children
• Complaint
A responsible provider of health care on the internet has to recognize patients’ rights

Health personnel and responsible conduct:
Health personnel shall conduct their work in accordance with the requirements to professional responsibility and diligent care...
- their qualifications
- nature of their work
- the situation in general

The Health Personnel Act, § 4

Responsible health care via internet? Relevant questions:
• Do you “know” the patient?
• Do you use e-mail?
• Do you see pictures, e.g. eczema?
• Do you ever recommend medical treatment on the basis of gathered information or are you just giving general health advice?

One crucial question:
Is it possible to provide responsible health care via internet to patients you “do not know”?

Privacy, confidentiality and security
• A great concern and a big issue
• Health information is sensitive information
• Processing personal data requires the best security systems
Directive 95/46EC: Directive on the protection of individuals............

Some current barriers:
• Immature technical solutions (processing of personal data)
• Confusing guidelines/advice concerning responsible conduct (health legislation)
• Lack of unambiguous criteria for the categorizing of web-sites
• Cross-border practice and liability
Some possible ways of regulating:
- To pass new acts
- To pass amending legislation
- Extensive interpretation of relevant acts and provisions
- Separate legislation for health-related web-sites
- International cooperation/international agreements

Some possible future prospects:
- Good security systems
- Responsible users/patients via Internet
- Experienced users/patients who demand and use a wide range of health-related services on the internet
- Experienced providers who have the skill to consider which services are suitable on the internet
- All the others

...
Federal and State Tensions in eHealth Regulation

Nicolas P. Terry
Professor of Law and Co-Director
Center for Health Law Studies, Saint Louis University
terry@slu.edu - http://law.slu.edu/healthcenter/

14th World Congress on Medical Law, 14 August 2002, Maastricht

eHealth Regulation

- Post-dot.com maturity for technologically-mediated care
- Current regulatory environment...

- Declining attention to the quality of health-related web sites; energies deflected by utilization of technology to improve bricks-and-mortar health care in face of medical error "crisis"
- Increasing regulation of cross-border medical and pharmacy practice apparently aimed at online prescribing
- Relative failure to articulate coherent, comprehensible and principled approach to ensuring the Privacy and Security of medical records

Federal Policies

- Use technology to improve medical quality
  - Directly by reducing medical error
  - Indirectly by decreasing consumer information costs through increased reporting, analysis and disclosure
- Encourage interoperability and technology-led efficiency in interstate medical and insurance markets

- Ensure consumer confidence by reducing privacy and security externalities in exchanges of health information
- Encourage the use of technology to increase efficiency of federally-funded intrastate services
- Improve cross-border practice in order to prevent distortions in market conditions between states

State Policies

- Leverage health care technologies to provide a greater range of intrastate services, reduce costs and reach underserved populations
- Maintain state control over quality regulation under inherent (or "police") powers
- Licensure and discipline machinery
- Malpractice, autonomy and confidentiality rules
- Counter negative non-pecuniary externalities suffered by their citizens when neighbor states fail to enforce licensure/quality
- "Parochial Protectionism"

Tensions

- Increasingly, these policies and their extant or proposed legal mechanisms suggest renewed tensions between state and federal systems
- Examples:
  - "Telemedicine" regulation
  - Duplicative or "Cooperative" health privacy regulation
- Suggestions:
  - Direct, "immediate" telemedicine and federal health privacy should only be undertaken when problems not solvable for federal regulation continue to "wreak the baby out with the bathwater"
  - States, particularly private, law options remain important and viable

State "Telemedicine" Regulation

- New definitions of "telemedicine" that...
  - Invade state jurisdiction over traditional medical practice
  - Create de facto dual federal/state regulation
  - Compromises due to divergent state policies relating to privacy and security
  - Challenges...a "state's right to define its own laws to accomplish its legitimate policy objectives"
- "Additional layers" of "telemedicine"
  - Medical malpractice (albeit generally limited)
  - Record-keeping requirements
  - Various consent requirements
  - Specialty-based insurance requirements
  - "Parochial Protectionism"?

- Specialized or "parochial" licensing for practitioners who practice electronically across state lines
On-line Prescribing & Regulatory Ambivalence

Regulatory Actions
- Physician advocates of hormone treatments to combat "male menopause" guilty of professional misconduct through "irresponsible" use of a website (Androscreen.com)
- California—Doctor taking photographs of dying cancer patient, Berthiaume’s Estate v. Pratt, 365 A.2d 792 (Me. 1976)
- Nurse’s husband watched delivery…failed on facts because no proof of intentional intrusion, Knight v. Penobscot Bay Medical Center, 420 A.2d 915 (Me. 1980)

Federal & State Privacy Regulation
- State—Common Law—Invasion of Privacy
- Doctor taking photographs of dying cancer patient, Berthiaume’s Estate v. Pratt, 365 A.2d 792 (Me. 1976)
- Nurse’s husband watched delivery…failed on facts because no proof of intentional intrusion, Knight v. Penobscot Bay Medical Center, 420 A.2d 915 (Me. 1980)

PIHI Disclosure Model
- Disclosure Standards
  - Minimum Necessary
    - Use—Treatment—Required by Law Enforcement
  - Required
    - ICD—Biomed—Public Health—Law Enforcement—Judicial Author
  - How?
    - Covered Entities
      - Health Care Providers
        - Conducting HIPAA Transaction
      - Health Plans
      - Clearinghouses
      - Business Associates

State Health Privacy Law
- Common Law—Invasion of Privacy
  - Doctor taking photographs of dying cancer patient, Berthiaume’s Estate v. Pratt, 365 A.2d 792 (Me. 1976)
- Common Law—Breach of Confidence
  - Nurse’s husband watched delivery…failed on facts because no proof of intentional intrusion, Knight v. Penobscot Bay Medical Center, 420 A.2d 915 (Me. 1980)
State Health Privacy Laws

- Public health statutes with correlate confidentiality guarantees
  - Mental Health Parity, etc.
  - Genetic information
  - Other
- Little Used Uniform Law
  - National Conference of Commissioners on Uniform State Laws, Uniform Health-Care Info. Act (1985) adopted in CA, WI
- States with comprehensive medical privacy laws (CA, RI, WI)
- Partial or cooperative preemption model
  - States possess sovereign authority to enact laws of more importance
  - Federal consent retreat (NPRM)
  - State HIPAA "tweaking" (Tex)
- New State laws not solely US phenomenon
  - French Medical Records Act 2002, Loi n° 2002-303 du 4 mars 2002 art. 11
  - Victoria Health Records Act 2001

Concluding Thoughts

- Dormant Commerce clause
  - Judicial correlate to Art. 1 US Const. giving Congress the power to regulate commerce "among the several States"
- Applied in Internet cases involving Spam, Pornography, cross-border Wine sales, automobile distribution, etc.
- Strict scrutiny for facial discrimination between interstate and intrastate regulation of commerce (protectionism)
- Balancing test (setting off legitimate state interests) in cases where state regulation impinges on cross-border commerce—here traditional licensure police power
- See generally Jack L. Goldsmith & Alan O. Sykes, The Internet and the Dormant Commerce Clause, 110 Yale L.J. 785, 817 (2001)
- Applicable?
  - Is there any substantial interference with interstate commerce when state statute requires out-of-state doctor or pharmacy to collect geographical information on patient and comply with local rules for prescribing purposes?
  - Telemedicine regulation that discriminates between interstate and intrastate practice?

Federal and State Tensions in eHealth Regulation

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Concluding Thoughts

- National licensure? Federal discipline?
  - Movement in that direction via reciprocity for nursing profession
  - Little comfort to be gained from new "front" opening up on medical error
  - State and federal error reporting safe harbor provisions
  - State--Pennsylvania Medical Care Availability and Reduction of Error (Mcare) Act
  - Federal: Bush Malpractice Proposals

Federal and State Tensions in eHealth Regulation

T6
14th World Congress on Medical Law,
14 August 2002, Maastricht

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Cf. UK proposal for no-fault
New patient roles and new legal challenges

Leif Erik Nohr, Norway

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**General trends**
- Increased expenditure on healthcare
- Citizens expecting more
- More focus on efficiency
- Rights for patient’s
- Empowerment
- Globalisation
- Consumerism
- Modern information- and communication technologies

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**Recent study**
- More use of the Internet for health purposes (from 19% to 31%)
- More people wanting to be able to contact their doctor via email (43%)
- Use of internet appears to supplement rather than replace ordinary health services. Health personnel will need to respond to Internet-generated expectations and behaviour.
  (Source: Norwegian Medical Journal, 2002;122)

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**Some characteristics**
- Individuals are better educated about health care.
- Quick and easy access to information through the Internet
- Tomorrows (health) consumers will be adversarial, fickle and impatient
- One size will fit no one
- More active patients
  (Source: PWC, "Health Cast 2010")

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**New focus**
- No longer "the patient in focus", but health personnel and services in focus of the patient’s critical and demanding eyes.
Doctor - patient relationship

The responsible obligated doctor
The cooperating doctor, the consultant
The passive reciever

Information, participation, patient rights

The e-health consumer

- Healthy
- Wealthy
- Wise
- Technologically savvy
- Expecting more
- Take action to get action

(Source: DeloitteTouche “Winning the Loyalty of the E-HEALTH CONSUMER”)

Key elements

- Choice
- Flexibility
- Individuality

Subjects of change

- Organisations
- Institutions
- Authorities
- Money
- Professions
- Patients
- Legislation

Challenges

- Weakened national legislation
- Weakened supervising authorities
- Rigid legislation vs. consumer demands
- Jurisdictional problems
- Licensing
- Patient’s Rights

Challenges (cont.)

- How and to what degree can legislative protection of patients be provided?
  - Patient’s left to their own devices?
- The value of patient’s rights
  - From patient’s rights to consumer protection – or both?
New possibilities

• More and better information to patients
• More educated patients
• Real cooperation
• New means for patient-doctor contact/communication
• Real second and third and fourth opinion
• Networks
• The best possible treatment
• Access and equity

Actions and measures

• New thinking
  – from protectionism to consumerism
• Pan-national initiatives
• Global challenges – global action
• Development of patient's rights
  – Pan-European rights
• New notion of quality

Actions and measures (cont.)

• Contracts rather than acts?
• Quality assessment of information
• Education/training
  – Of professions
  – Of patients
• Facilitating cross-border communication

A concern

• When we develop or create a global health care market for the healthy, wealthy and wise, what impact will this have on the already huge gap between those with money and those without, both within a country and on a global level?