

Definition Of Telemedicine

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What is telemedicine?

" Telemedicine, a term coined in the 1970s, which literally means "healing at a distance" (1), signifies the use of ICT to improve patient outcomes by increasing access to care and medical information. Recognizing that there is no one definitive definition of Telemedicine - a 2007 study found 104 peer-reviewed definitions of the word (2)- the World Health Organization has adopted the following broad description ". (543)

Definition of telemedicine:

" Telemedicine is the remote treatment of patients by medical professionals through the use of telecommunication tools such as telephones, smart phones, and computers. Predicted to be worth more than 34\$ billion by the end of 2020, the convenient and efficient nature of telemedicine makes it a profitable and worthwhile venture for healthcare leaders and professionals to invest in ". (544)

The American Telemedicine Association (ATA) defines "telemedicine" this way:

⁵⁴³ – Telemedicine, opportunities and developments in member states. Report on the second global survey on Health Global observatory for e Health series–volume 2.

⁵⁴⁴ – The physician's guide to adding telemedicine to your practice (2) 2016 bizmatics, INC.

The use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology. ⁽⁵⁴⁵⁾

Telemedicine can be defined, according to the European Commission, as "the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients' (1).

States alternate between using the term "telemedicine" or "telehealth". In some states both terms are explicitly defined in law and/or policy and regulations. In some cases, "telehealth" is used to reflect a broader definition, while "telemedicine" is used mainly to define the delivery of clinical services. Additional variations of the term, primarily utilizing the "tele" prefix are also becoming more prevalent. For example, the term "telepractice" is being used frequently as it relates to physical and occupational therapy, behavioral therapy, and speech language pathology. "Telesychiatry" is

⁵⁴⁵ – Dana Murphy, what we're learning from the pla data sharing project, inside medical liability on line 2 July 2015, p. 2.

also a term commonly also adopting definitions of telehealth specific to their particular profession. In some cases, creating many passed legislation encouraging each Board to adopt their own definition of the term "telehealth". This has the potential to add to the already complex telehealth policy environment. ⁽⁵⁴⁶⁾

Telemedicine is broadly defined as the delivery of a health care service using electronic communications, information technology or other electronic or technological means to bridge the gap between a health care provider who is located at a distant site and a patient who is located at an originating site. The term does not include "the use, in isolation, of audio-only telephone conversation, electronic mail, instant messaging, phone text or facsimile transmission".

Telehealth is defined as the use of information and communications technologies, including telephones, remote patient monitoring devices or other electronic means, to support clinical health care, provider consultation, patient and professional health-related education, public health, health administration and other services. ⁽⁵⁴⁷⁾

⁵⁴⁶ – Mario Gutierrez: The centre for connected health policy is program of the public health institute, 2017.

⁵⁴⁷ – Nathaniel Lackt man August, 15, 2017. 11, PMEDT Law 360, New York (August 15, 2017, 2, 11 PM.EDT).

What providers need to know about NJOS Telemedicine law.

Telemedicine is now mainstream: the numbers speak for themselves. According to a recent industry report, the global telemedicine market is expected to be a \$35 billion industry by 2020. A separate report found that the market for telemedicine technologies was approximately \$18 billion in 2014, and expected to grow at a compounded annual growth rate of approximately 19 percent. The American Telemedicine Association estimates a majority of hospitals now use some form of telemedicine. Just two years ago, there were approximately 20 million telemedicine video consultations and that number is expected to increase to about 160 million by 2020 a 700 percent increase. ⁽⁵⁴⁸⁾

First and foremost, telehealth is a collection of means or methods, not a specific clinical service, to enhance care delivery and education. Ideally, there should not be any regulatory distinction between a service delivered via telehealth and a service delivered in person. Both should be held to the same quality and practice standards. The "tele-" descriptor should ultimately fade from use as these technologies seamlessly integrate into health care delivery systems.

While "telemedicine" has been more commonly used in the past, "telehealth" is a more universal term for the current broad array of applications in the field. Its use crosses most health service

⁵⁴⁸– Arthur J. Gallagher & Co. Medical Professional liability Risks of Telemedicine February 2017, p. 2.

disciplines, including dentistry, counseling, physical therapy, and home health, and many other domains. Further, telehealth practice has expanded beyond traditional diagnostic and monitoring activities to include consumer and professional education. ⁽⁵⁴⁹⁾

" While both telehealth and telemedicine are recognized to be subsets of the broader electronic health system "e-health", no consistent definition for telehealth or telemedicine has been adopted in literature or practice. Some organizations distinguish between the two, while others use the terms interchangeably". ⁽⁵⁵⁰⁾

How does Telehealth Work? ⁽⁵⁵¹⁾

"Today, telehealth encompasses four distinct domains of applications. Note, however, that each state Medicaid program and private insurer varies in its use and reimbursement of these applications. These are commonly known as:

- Live Videoconferencing (synchronous): Live, two-way interaction between a person and s provider using audiovisual telecommunications technology.

⁵⁴⁹ – California Telehealth, Resource centre, op, cit, p 11.

⁵⁵⁰ – Health Policy brief, looking ahead understanding Telehealth in ohio April, 2013.

⁵⁵¹ – California Telehealth Resource centr. Telehealth Reimbursement Guide for California, 2016, p. 12.

- Store-and-Forward (Asynchronous): Transmission of recorded health history through an electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside of a real-time or live interaction.
- Remote Patient Monitoring (RPM): Personal health and medical data collection from an individual in one location via electronic communications technologies, which is transmitted to a provider in a different location for use in care and related support.
- Mobile Health (mHealth): Health care and public health practice and education supported by mobile communication devices such as cell phones, tablet computers, and PDAS. Applications can range from targeted text messages that promote healthy behavior to wide-scale alerts about disease outbreaks, to name a few examples.

History of Telemedicine:

A market research report by Mordor Intelligence, "The global market for telemedicine will be worth more than \$34 billion by the end of 2020". Currently, North America account for more than 40% of the global market. Telemedicine is the future and will transform the U.S healthcare system.

In April 1924, the magazine "Radio News" imagined a "radio doctor", who is a doctor that listens to a patient through sound and live picture. In 1959, clinicians began finding medical uses for video

communication. They used two-way television to transmit neurological examinations across campus to other students, where they established a link with the state Hospital to provide diagnosis of difficult cases, research seminars, and neurological exams. These programs arose because people that lived in remote populations did not have the luxury of different health services. ⁽⁵⁵²⁾

In 1967, University of Miami physicians used voice radio channels to transfer electrocardiographic rhythms from fire units to hospitals in rescue situations. Additionally, telemedicine is especially useful for nursing home.

Origins and history:

Historically, telemedicine can be traced back to the mid to late 19th century with one of the first published accounts occurring in the early 20th century when electrocardiograph data were transmitted over telephone wires. Telemedicine, in its modern form, started in the 1960s in large part driven by the military and space technology sectors, as well as a few individuals using readily available commercial equipment. Examples of early technological milestones in telemedicine include the use of television to facilitate consultations between specialists at a psychiatric institute and general practitioners

⁵⁵²- The Physician's Guide to adding. Telemedicine to your practice, 2016 Bizmatics, inc, pp. 4-5.

at a state mental hospital (7), and the provision of expert medical advice from a major teaching hospital to an airport medical centre. ⁽⁵⁵³⁾

BENEFITS OF TELEMEDICINE: ⁽⁵⁵⁴⁾

There are three main benefits of telemedicine that impact the world of medicine and healthcare delivery.

It provides benefits to various groups. Telemedicine eliminates distance as a factor in treating patients. Patients no longer need to drive to the doctor's office to receive medical advice. This also allows patients access to healthcare where it is not otherwise available. This, therefore, increases the quality of care received and reduces healthcare costs.

It allows more access to healthcare. Telemedicine does not only benefit the individual. It also allows healthcare professionals to access information quickly and efficiently. A medic on the battlefield can receive immediate information from a clinician with a higher level of skill, allowing him/her to provide a higher quality of care to their patients. By receiving this information quickly, you can drastically

⁵⁵³ – Report on the second global survey on eHealth, op, cit. p. 9.

⁵⁵⁴– Ruthe C. Ashley, RN, MSN, JD, attorney at law and healthcare consultant in Sacramento, CA.

reduce the mortality and morbidity rates. Also, quality trauma care depends on the timely, efficient and accurate flow of information at each step of the crisis management process. Telemedicine can provide the vehicle for this flow of information.

It improves healthcare quality. Telemedicine gives healthcare providers a chance to enhance their skills and expand their professional knowledge by linking providers with experts. A patient can visit his general practitioner and receive a consultation from an expert all in the same office visit. This saves time and money for the patient.

According to The New England Journal of Medicine, it takes an average of 20 days to secure an appointment with a physician where in only 20 minutes out of two hours will actually be spent with the physician and the remaining time is allotted for travel and waiting. In contrast, there is no travel nor wait time with telemedicine. In an effort to help healthcare institutions run more efficiently and reduce needless costs and foregone revenue associated with seeing and diagnosing patients, telemedicine has the ability to deliver services to the 20% of persons who account for 80% of health care expenditures. As stated by the U.S. Senate Committee on Finance, "Traditionally telehealth has been viewed as a tool to improve access to services, but interest is growing to see if telehealth has the potential to reduce healthcare

industry can adopt a more patient-centric approach by practicing telemedicine. ⁽⁵⁵⁵⁾

Telemedicine is also beneficial for patients because of its convenient health care, increased specialty access, and extended provider access. It allows patients to access their provider without the cost of travel and time, and offers a greater variety of specialties for specific diseases without needing to travel for distances. For simple tasks, such as contacting a doctor about over the counter treatment, getting a prescription for something that's easily and readily identifiable, or getting an expired prescription re-authorized, it can be advantageous to be with a telemedicine provider. In addition to this, patients can consult their providers and gain a treatment plan in minutes when in critical need as compared to traveling to their doctor. ⁽⁵⁵⁶⁾

⁵⁵⁵– The physician's Guide to adding Telemedicine to your practice (2) 2016 Biz matics, inc, p. 5.

⁵⁵⁶– The Physician`s Guide to adding Telemedicine to your practice (2) 2016 BIZ matics. Inc. p5.

Licensure And Telemedicine

Licensure:

Although many telemedicine interactions already cross state and national. There is much discussion about standardizing licensure and certification requirements to allow practitioners to perform services across state lines without having to undergo reexamination and/or refilling of fees. The Federation of State Medical Boards has drafted model legislation requiring full and unrestricted licensure of out of state telemedicine providers whose practice extends into these states. (557)

Congressional interest in the licensure of telemedicine providers has taken the form of requests for information and proposed legislation, but to date no action has been taken. In May 1995, Rep. Ron Wyden (D-OR) offered and withdrew an amendment that would have prohibited states from "directly or indirectly restricting interstate commerce by prohibiting any licensed physician from conducting a consultation with a licensed provider in another state using any advanced telecommunications service... "Then Rep. Wyden's action led, in part, to the call for this report. In addition, Senators Kent Conrad (D-ND) and Bob Kerrey (D-NE) introduced a bill directing the Secretary of Health and Human Services to make an annual report to Congress on licensure barriers to telehealth. This bill was introduced on the last day of the 1996 Legislative session and no

⁵⁵⁷ – Scott A Edeistein. JD. MPA, op, cit, p. 63.

action was taken. The issue may be re-examined when Congress meets again in 1997. ⁽⁵⁵⁸⁾

Limited Licensure:

A limited licensure system would be a modification of the current system. Health professionals would be required to obtain a license from each state in which they practiced. However, the health professional would have the option of obtaining a limited license that allows the delivery of a specific scope of health services under particular circumstances. This system would limit the scope of practice rather than the time period for practice as is currently the case with some full and unrestricted license would be somewhat less burdensome than for full licensure. Each state would continue to establish its own standards for licensure.

Limited licensure requires each state legislature, acting on its own, to adopt such a system. Limited licensure could reduce the administrative burdens on out-of-state health professionals who would otherwise obtain full license. Clinicians will continue to confront the hurdle of trying to comply with disparate state licensure requirements

⁵⁵⁸– Telemedicine report to congress legal issues–licensure and telemedicine January 31, 1997.

because each state would continue to establish its own standards for licensure. ⁽⁵⁵⁹⁾

Historically, interstate physician-to-physician communications have subject to licensing requirements. These communications can take a variety of forms including the mailing of x-rays, clinical histories and pathological and laboratory specimens for evaluation and interpretation, and oral or written inquiries to another out-of-state physician involved in the patient's care or in interstate communications, the consultative request to a physician with special expertise. In these interstate communications, the consulted physician or other health professional is regarded either as practicing medicine only in his or her home state or as exempt from licensure under the "consultation exception" in the patient's state. ⁽⁵⁶⁰⁾

There are many scenarios in which licensure issues arise. For example, a patient begins a video consult in one state while a passenger in a vehicle that then crosses into another state prior to the consult being completed. There are many other examples. Telemedicine providers using traditional technology, such as a land line telephone, must confirm the exact patient location before matching the patient to a duly licensed professional. Most

⁵⁵⁹ – Helen Gregg. Op. cit.

⁵⁶⁰ – Telemedicine report to congress legal issues, licensure and telemedicine, January 31, 1997.

telemedicine providers employ physicians and other professionals that carry licenses in multiple states to help address these potential concerns. ⁽⁵⁶¹⁾

Jurisdictional diversity and licensure: Physicians and others who provide care to patients in a different legal jurisdiction than their own- usually, this means in another state-engage the historical, complex area of law called "conflict of laws". If a practitioner licensed only in jurisdiction A treats a patient in jurisdiction B, he may be violating B's laws. Or, a practitioner in A who violates a contract or treats a patient in B negligently may incur liability in B, A, or both. ⁽⁵⁶²⁾

In light of the confusion in regard to jurisdictional diversity, many healthcare professionals have concluded that the only way individuals can utilize telemedicine with equanimity is to:

- Provide telemedicine services only to patients who reside in the state where they are licensed.
- Obtain the necessary license to practice medicine/nursing in every state in which they may wish to use telemedicine.
- Practice within the parameters of the narrow exemptions most states have established to their "unauthorized practice" laws for out-of-state physicians and nurses who act as (infrequent)

⁵⁶¹ – Arthur J. Gallagher & Co. op. cite. P. 3.

⁵⁶² – Dana Murphy, op, cit, p. 3.

consultations to in-state practitioners (at the in-state physician's request) or who assist in emergencies. ⁽⁵⁶³⁾

There is inconsistency, from one state to another, in how telemedicine is regulated. Not all states address telemedicine and the related issue of licensure. However, there are useful complications of state laws on licensure and scope of practice available online. In April, the Federation of State Medical Boards (FSMB) announced an initiative to explore the use of interstate compacts to simplify telehealth licensing. ⁽⁵⁶⁴⁾

International Telemedicine: ⁽⁵⁶⁵⁾

International Telemedicine continues to grow. There are many examples from American expatriates using virtual health care services provided by physicians located in the U.S. to Americans seeking less expensive care via telemedicine from health care providers located outside the U.S. International cross border treatment implicates complex licensure issues. In other words, health care provider licensure will be a major concern in international telemedicine as the rendering of health care provider could potentially violate a country's health care law and policies.

⁵⁶³ – Ibid.

⁵⁶⁴ – Dana Murphy, op. cit. p. 3.

⁵⁶⁵ – Arthur J. Gallagher & Co. op. cit. p. 4.

Telemedicine

And

Consent of patient

Service provider must: ⁽⁵⁶⁶⁾

Obtain informed consent of patient. Ensure patient understands country of origin principle if applicable. Ensure secure storage, processing and transmission. Ensure medical staff are fully briefed.

Doctor must: ⁽⁵⁶⁷⁾

Ensure consent is informed, specific and freely given. Ensure patient knows who has access to what data and for what purpose, ensure that nominative data is treated securely. Ensure that "technical" data is treated securely or anonymised. Ensure that specific consent is obtained for any research.

Informed Consent:

Standard informed consent principles mandate physicians to provide adequate information to their patients to enable the patients to make informed decisions regarding their diagnosis and treatment. If telemedicine forms an integral part of the care being provided, it may be necessary to disclose information about the telemedicine system, the potential risks and benefits of telemedicine, and the limitations of the equipment and telecommunications technology. Practitioners who have ultimate responsibility for care and primary diagnosis should

⁵⁶⁶ – Petra Wilson, legal and Ethical issues in telemedicine Ehra 25th March, 2010.

⁵⁶⁷ – Petra Wilson, op. cit. p.

obtain the patient's oral and written informed consent before the telemedicine encounter. ⁽⁵⁶⁸⁾

Rules governing the establishment of a physician-patient relationship may be another obstacle to the growth of telehealth services. In many states, a physician-patient relationship is created once a practitioner has an opportunity to take a patient's medical history and conduct an in-person physical exam. As a result, in a majority of states, physicians are prohibited from remotely prescribing medications without first conducting an in-person physical exam. ⁽⁵⁶⁹⁾

When a patient is being treated remotely, the informed consent process should include any pertinent benefits, risks, and alternatives that are unique to the telemedicine setting.

The patient should understand the limitations of telemedicine and that the physician may decide that it is inappropriate to evaluate and treat, or continue to treat, the patient through telemedicine. While there is no one informed consent process that would be applicable to all telemedicine encounters, the American Telemedicine Association guidelines include some recommendations that are relevant in many cases.

⁵⁶⁸ – Scott A. Edelstein, JD. MP4, op. cit. p. 64.

⁵⁶⁹ – Dana Murphy, op. cit. p. 4.

- The provider should set appropriate expectations in regard to the telemedicine encounter. This may include prescribing policies, scope of services (including the structure and timing of services), communication and follow-up.
- Topics to be reviewed with patients include confidentiality and the limits of confidentiality in electronic communication, an agreed upon emergency plan particularly for patients in setting without clinical staff immediately available, the process by which patient information will be documented and stored, the potential for technical failure, procedures for coordination of care with other professionals, a terminated and a referral made to in-person care. ⁽⁵⁷⁰⁾

The physician using telemedicine should obtain the patient's informed consent before providing care via telemedicine services. In addition to information relative to treatment, the patient informed of the risks and benefits of being treated via telemedicine. This includes how to receive follow-up care or assistance in the event of an adverse reaction to the treatment in the event of an inability to communicate as a result of technological or equipment failure. The patient retains the right to withdraw his or her consent at any time.

⁵⁷⁰ – Copic insurance, Telemedicine and liability issues in Nebraska, July, 2015, p.2.

Note that the existence of a relationship between the physician and the patient must be established before an MPL action can be filed. ⁽⁵⁷¹⁾

Obtain Informed Consent. There are two types of informed consent to be aware of:

- As a consultant to physician or other healthcare professional: You need to ensure the patient/client has full disclosure and has consented to your consultation. You are less likely to have licensing barriers if you have no direct contact with the patient/client. Also, you need to operate within your pre-determined policies, procedures and protocols (PPP's). (Note: The state of California requires that healthcare practitioners who have ultimate authority over care or primary diagnosis of patient must obtain verbal and written informed consent from the patient or patient's legal representative prior to delivery of healthcare via Telemedicine).
- Relationship between you and client/patient: You need to obtain consent in writing or on audiotape. Make sure to give full disclosure of all known facts in which the client can give informed consent about, including: A description of all potential risks and benefits of telemedicine, all existing laws regarding patient access to medical information and copies of medical records, no dissemination of patient identifiable images or information from

⁵⁷¹ – Dana Murphy, op. cit. p. 5.

the telemedicine session to researchers or other entities without consent becomes a part of the medical record. ⁽⁵⁷²⁾

⁵⁷²– Ruthe C. Ashley, R.N. MSN. JD. Op. cit. p. 1.

Telemedicine And Physician liability

(Editor's note: Part 1 of his Guest Editorial was published in the October/November 2015 issue, part 3 will be published in the January 2016 issue).

" Many state medical boards have adopted the following or similar guidelines for physicians using telemedicine technologies in the delivery of patient care, regardless of whether a patient-physician relationship existed before the telemedicine encounter: ⁽⁵⁷³⁾

1. A physician must be licensed by, or under the jurisdiction of the medical board of the state where the patient is located. Therefore, the practice of telemedicine occurs where the patient is located when telemedicine technologies are used. Physicians who treat or prescribe through online sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients receive care.
2. When an existing patient-physician relationship does not exist before the telemedicine encounter, a physician has the obligation to take the appropriate steps to establish an acceptable patient-physician relationship and, while each circumstance is unique, such patient-physician relationships may be established using telemedicine provided that the standard of care is met.

⁵⁷³– Steven T. Kmucha, MD.JD. Facs, Guest Editorial, Ent. Ear & Throat journal, December 2015. www.entjournal.com

3. The physician must document the collection of relevant clinical history and a medical evaluation consistent with the presentation of the patient to establish diagnoses and identify underlying and potentially conflicting/confounding medical conditions and/or contraindications to the treatment recommended/provided before providing recommendations, treatment, prescriptions, etc. Treatment and consultation recommendations made via telemedicine will be held to the same standards of appropriate practice as those in a traditional (in-person encounter) setting. Treatment, including the issuance of a prescription based solely on an online questionnaire, does not currently constitute an acceptable standard of care in any jurisdiction.
4. Evidence documenting and memorialized appropriate patient informed consent for the use of telemedicine must be obtained and maintained. Appropriate informed consent should, as a baseline, include: (a) identification of the patient, the physician.

Malpractice Liability is always present in relationship between the dietetics practitioner and client/patient. It is the greatest unknown barrier to telemedicine. The main question raised is "which state law should be used?". Should it be the state where the practitioner resides and dispenses information or the state where consultation takes place with patient and/or physician? One possible way to determine jurisdiction. Would be to contact the Centers for Medicare and Medicaid Services (CMS-previously called the Health Care Financing

Administration or "HCFA"). CMS reimburses Medicare providers according to the Geographical Practice Cost Index and the patient is "transported" to the practitioner. Also, the Physician's Code of Ethics and AMA Web Ethic Guidelines are also factors in setting this standard".⁽⁵⁷⁴⁾

Strict Liability:

"Manufacturers should vigorously defend the traditional product/services distinction. From a policy perspective the nature of computer programming should be recognized as a service: "Software's complexity makes it virtually impossible to prevent some defects (called "bugs") from showing up in programs, even when the software has been on the market for several years. Debugging, in fact, may be the most costly aspect-in both time and dollars-of software development. An argument that may be persuasive here is that telemedicine concerns, like software companies, provide ongoing services, not finished products: "Developing a computer program is a continuing process. Rather than a single act". Strict liability is inappropriate for a "product" in continual evolution".⁽⁵⁷⁵⁾

Tort:

⁵⁷⁴ – Ruthe C. Ashley, RN. MSN. JD. Op. cit. p. 1.

⁵⁷⁵ – Joseph P. Mcmenamin, op. cit. p. 30.

Preemption. A "medical device" is "an instrument, apparatus, implement, machine, contrivance... Or other similar or related article, including any component, part or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease". As of this writing, the Food and Drug Administration (FDA) has neither approved nor disapproved technology employed in telemedicine practice, but surprising that the FDA has taken the position that devices or software used in aid of telemedicine practice are "devices" within the meaning of the Federal Food, Drug, and Cosmetic Act.⁽⁵⁷⁶⁾

In the law of negligence, there could be no recovery no matter what harm had come to plaintiff, if the defendant had acted reasonably-which in general was ascertained by comparing his conduct with that of others in his field under similar circumstances. Strict liability is a theory originating in the law of products liability, it provides that one who sells a product in defective condition unreasonably dangerous to the consumer, provided that the defendant is in the business of making or selling such products, and that the product reaches the consumer in a condition substantially unchanged from that in which it was sold. In strict liability theory, the defendant can be found liable even if his conduct was similar to that of other, reasonably prudent actors within the same field or discipline. One

⁵⁷⁶ - Joseph, P. Mc. Menamin, op. cit. p. 29.

rationale for this approach is that manufacturers and sellers of products are well situated to spread the risks attendant to the use of their products by developing and utilizing a pricing structure that takes such risks into account. A plaintiff seeking to advance a strict liability theory might possibly proceed under 402A of the Restatement (Second) of Torts. ⁽⁵⁷⁷⁾

But the fact is that presently the EU has not yet created a harmonized set of rules regarding tort and criminal medical liability, nor is it conceivable that it will happen while the distribution of competences remains the same. Nevertheless, on the beginning 90s (last century's, that is) the EU proposed a Directive dealing with the healthcare providers liability (OJC 12/8, 1991), but it was not approved and no other proposal of that kind has been submitted. Therefore, it is up to each Member State to regulate this issue, just as it is up to each Member State to define the qualifications and requirements to practice medicine and consequently telemedicine. According with a Staff Document of the European Commission an healthcare professional operating in telemedicine only needs to be registered in the country where he is established and to comply with the requirements imposed in that legal order. But even the most basic questions, such as the definitions from each national legal order

⁵⁷⁷ – Joseph P. Mc Menamin, op. cit. p. 29

(some legal orders do not even hold a definition for medical act, such as the Portuguese one).

That stands in stark contrast to most other states, which have been working to adjust their laws to accommodate new telemedicine technologies. Indiana, for example, passed a law in March that allows doctors to establish a doctor-patient relationship over video conference, and even prescribe medications, without requiring the patient to go to clinic first or see the doctor in person. Same goes for Virginia, whose medical board last year issued guidelines for telemedicine that allow a doctor-patient relationship to be established remotely as long as the standard of care is met. Like Indiana and a host of other states, Virginia also allows doctors to prescribe medication remotely, "at the professional discretion of the prescribing practitioner". And in all these states, patients can send pictures, videos, or texts messages to doctors they have never met before. ⁽⁵⁷⁸⁾

Provider-Patient Relationship: ⁽⁵⁷⁹⁾

A valid provider-patient relationship may be established via telemedicine or telehealth without an in-person exam. Moreover, New Jersey licensing boards are prohibited from passing regulations that

⁵⁷⁸ – John Daniel Davidson October, 4,2016, 3 comments How a law suit could impact the future of health care in Texas, p. 2.

⁵⁷⁹ – Nathaniel Lactman, August, op. cit. p.2.

would require an in-person exam as a prerequisite to delivering telemedicine or telehealth services. A valid provider-patient relationship must include, at a minimum, the following:

- Properly identifying the patient using, at a minimum, the patient's name, date of birth, phone number and address. The provider may additionally use the patient's assigned identification number, social security number, photo, health insurance policy number or other appropriate patient identifier associated directly with the patient.
- Disclosing and validating the provider's identity and credentials, such as the provider's license, title and, if applicable, specialty and board certifications.
- For an initial consult with a new patient, the provider must review the patient's medical history and any available medical records before initiating the telemedicine consult. (For telehealth consults conducted in connection with a pre-existing provider-patient relationship, the provider may review the information with the patient contemporaneously during the consult).
- The provider must determine whether or not he/she will be able to meet the standard of care. This determination must be done prior to each unique patient consult.

Physician's credentials: (b) types of transmissions permitted using telemedicine (e.g., appointment scheduling, patient educational materials, prescription refills, etc.), (c) the patient's agreement that the physician (in his or her sole discretion) determines whether the

condition being diagnosed and/or treated is appropriate for a telemedicine encounter, (d) details of the security measures taken with the use of telemedicine such as encryption, password protection, authentication technologies, and potential risks to privacy of protected patient health/healthcare information notwithstanding such security measures, (e) a hold-harmless clause for information lost because of technical failures, and (f) clear documentation of patient consent for the release of any patient-identifiable information to any third party. (580)

Medical malpractice can be defined as professional misconduct in improperly discharging professional duties, or failing to meet the standard of care of a professional. Various definitions of standard of care and professional duties have been provided by statute, regulations, and case law. The diverse nature of these definitions and their sources are further complicated by jurisdictional issues when applied in the area of telemedicine. The additional problem of the time delay between the event leading to a malpractice claim and the filing of the claim means that some problems may take up to two or more years before they become apparent. (581)

One potential factor that could lead to increased claims involves communication. Lack of communication is often the root cause of

⁵⁸⁰ – Steven T. Kmucha, MD. JD. Facs, op. cit. p. 466.

⁵⁸¹ – These Models, Elegal and Regulatory issues by these models.

many medical malpractice allegations and claims. Crico Strategies published a study in 2015 in which it analyzed 23.658 MPL (from 2009-2013), and concluded that 30 percent of these cases involved some form of communication failure. In the cases where communication was a factor, 55 percent involved a miscommunication may be impacted potentially leading to increased MPL liability exposure. ⁽⁵⁸²⁾

In a medical liability case, a physician is held to the standard of reasonable and ordinary care, defined as "that which health care providers, in the same community or in similar communities and engaged in the same or similar lines of work, would ordinarily exercise and devote to the benefit of their patients under like circumstances".

Although this hasn't been specifically addressed in Nebraska law, a practitioner will likely be held to the same standard of care as in a traditional encounter and not a "telemedicine" standard. The Federation of state Medical Boards, in its model telemedicine policy, takes this approach: "(A) physician using telemedicine technologies in the provision of medical services to a patient (whether existing or new) must take appropriate steps to establish the physician-patient relationship and conduct all appropriate evaluations. As such, some situations and patient presentations are appropriate for the utilization

⁵⁸² - Arthur J. Gallagher & Co. op. cit. p. 3.

of telemedicine technologies as a component of, or in lieu of, in-person provision of medical care, while others are not".⁽⁵⁸³⁾

Telemedicine providers seeking liability protection should purchase MPL insurance at the inception of the business and before patient encounters commence. As a rule, it is in the best interest of the telemedicine provider to purchase MPL insurance coverage that provides protection to all healthcare providers and the healthcare entity on a shared basis per occurrence and in the aggregate. The shared limits approach is more cost effective as opposed to having each individual limits. The shared limit approach also precludes a "clash loss" in which a claim naming multiple policies and multiple sets of limits.⁽⁵⁸⁴⁾

Physician-Patient Relationship:⁽⁵⁸⁵⁾

Formation of a physician-patient relationship is usually clear in the traditional practice setting, but it may not be as clear where a physician has no in-person contact with a patient or where the physician is advising another practitioner who is at the patient's location. Even if the physician is just advising another practitioner, the consultant may also be considered a "treating" physician if:

⁵⁸³ – Copic insurance, Telemedicine and liability issues in Nebraska, July 2015, p.1.

⁵⁸⁴ – Arthur J. Gallagher & Co. op. cit. p.3.

⁵⁸⁵ – Copic insurance, Telemedicine and liability issues in Nebraska, July, 2015, p1.

- The consultant interprets patient data such as labs, EKGs, or imaging studies.
- The consultant participates in diagnosing the patient and prescribing a course of treatment.
- The treating practitioner must rely on the consultant's expertise rather than exercising his or her judgment in treating the patient.

If a physician is being paid to provide consulting services, that may be a factor in determining whether the physician has a "contractual" obligation to the patient.

Liability considerations: ⁽⁵⁸⁶⁾

There are obviously privacy-related issues in play with telemedicine, whether it is conducted via the Internet, a mobile phone. Problems like identity theft persist, despite ever greater attempts at security. There may also be issues linked to discrepancies between self-reporting of data and the actual, measured values. Patients with diabetes, for example, may be tempted to relay to their healthcare professional blood glucose levels that are considerably better than what their glucometer actually shows.

No healthcare professional should forget the advantages of an in-person visit. There, the whole person is visible, and subtleties in

⁵⁸⁶ – Dana Murphy, op. cit. p.

physical condition and affect can be directly perceived, and queried if necessary.

Although the definitions of telemedicine and telehealth vary at the state and federal level, "telehealth" in Nebraska has been defined as the use of medical information electronically exchanged from one site to another, whether synchronously or asynchronously, to aid a health care practitioner in the diagnosis or treatment of a patient. It includes services originating from a patient's home or other location, asynchronously services involving the acquisition and storage of medical information at one site that is then forwarded to or retrieved by a health care practitioner at another site for medical evaluation, and telemonitoring. ⁽⁵⁸⁷⁾

⁵⁸⁷– Copic insurance Company, Telemedicine and liability issues in Nebraska, July, 2015, p. 1.

Telemedicine And Laws

Telemedicine Laws:

California:

- The Telemedicine Development Act of 1996 prohibits health plans from requiring a face-to-face visit if the service can be provided via telemedicine, The Telehealth Advancement Act, which became state law Jan.1,2012, expanded on the 1996 law to include a larger number of telemedicine services and ensure reimbursement parity.
- AB 1310 would prohibit the state's department of healthcare services from requiring a physician to physically be in California, The bill has been referred to the appropriations committee.
- California's Medicaid program recognizes and reimburses for store-and-forward telemedicine.
- A bill currently in the California legislature would allow store-and-forward technology for teledentistry. ⁽⁵⁸⁸⁾

New Jersey:

- S 2338 would require private payers, the State Health Benefits Commission and the school Employee's Health Benefits Commission to cover telemedicine services. The bill was introduced Aug.11, 2014.

⁵⁸⁸– Helen Gregg, Telemedicine laws and developments: A state-by-state analysis August 22, 2014/ print Email.

- Assembly bill 2161 would allow federally qualified health centers more flexibility in contracting with mental health providers for telemedicine services. The bill has been referred to a subcommittee.
- New Jersey is one of 26 states that have an informed consent policy for telemedicine.⁽⁵⁸⁹⁾

FDA Guidance Regarding Mobile Medical Applications and MDDS:

With passage of the Food and Drug Administration Safety and Innovation Act in 2012, the FDA was given approval to go forward with its regulatory work on medical apps. In February 2015, the FDA issued guidance to provide clarity for mobile medical app manufacturers and other interested parties, which stated the FDA's intent to exercise enforcement discretion on mobile medical apps that pose a low risk to patients' safety. Additionally, in February 2015, the FDA also issued guidance stating that it would practice enforcement discretion on MDDS devices. MDDS is a device that is intended to transfer, store, convert or display medical device data without controlling or altering the functions or parameters of any connected

⁵⁸⁹ – Helen Gregg, op.cit.p2.

medical devices. An MDDS may include software, electrical hardware, modems, interfaces, and a communications portal. ⁽⁵⁹⁰⁾

Telemedicine in the UAE:

In order to market healthcare services in the UAE, a healthcare provider must establish a legal presence and hold a commercial license to do business in the UAE (or in a free zone in the UAE) and also hold the relevant healthcare provider license. The authorities that regulate the licensing of healthcare in Abu Dhabi, Dubai and Dubai Healthcare City are: Abu Dhabi Health Authority (HAAD), Dubai Health Authority (DHA) and Dubai Healthcare City Authority (DHCCA), respectively.

Abu Dhabi:

Abu Dhabi has a sophisticated regulatory regime for telemedicine and has issued a telemedicine license to the Abu Dhabi Telemedicine Centre. However, telemedicine licensing has been suspended in Abu Dhabi for the time being and it is not known if or when such suspension will be lifted. ⁽⁵⁹¹⁾

⁵⁹⁰ – Food and Drug Administration and state Regulations, April 20, 2011.

<https://www.telehealthresourcecenter.org/toolbox-module/food-and-drug-administration-and-state-regulations>

⁵⁹¹ – By Christopher Lester and Donya Fredj on May 25, 2016 Posted in Healthcare, Technology, United Arab Emirates.

EHealth applications in Egypt: ⁽⁵⁹²⁾

The WHO survey on eHealth applications conducted in 2009 covers telemedicine, mHealth, and elearning. In this survey, Egypt reported that telemedicine enabling actions have not been implemented yet (25).

However, the Egyptian government represented by MCIT and MOH have initiated several EHealth programs to afford better diagnostic and health services to a wider segment of the Egyptian society. The MCIT role is facilitating the integration of ICT in health services and building the required ICT capacities in the health sector.

4.1 Problems and challenges facing telemedicine in Egypt: ⁽⁵⁹³⁾

However, the majority of telemedicine projects in Egypt face many problems and challenges such as (29), (30):

<http://www.al-mirsal.com/2016/05/25/telemedicine-in-the-uae/>

⁵⁹²– Rada Hussien. Aly Khalifa, Telemedicine in Egypt, Swot analysis and future. Trends. GMS Medizinische Informatik, Biometrie und Epidemiologie 2012, vol.8(1). ISSN 1860-9171

⁵⁹³– Rada Hussein. Aly Khalifa, op. cit. p.6.

- Lack of patients' awareness and acceptance of receiving healthcare services via telemedicine networks and applications.
- Inability to sustain the functionality of the project due to shortage of both financial and legalization frame-works.
- Lack of professional calibers as well as capacity building programs.

Telemedicine networks frequently are owned and/or operated by a separate legal entity that contract with physicians to provide teleconsultations. This arrangement could be problematic in states with laws that prohibit the practice of medicine by unlicensed individuals or corporations. These laws have been interpreted to prevent the employment of physicians by a business corporation.⁵⁹⁴

Some states exempt HMOs, physician groups organized as professional corporations, and hospitals from this prohibition. This prohibition is intended to prevent physicians and nonphysicians from engaging in financial relationships in which a shared focus on profits could adversely affect the quality of medical care.⁽⁵⁹⁵⁾

Written policies and procedures should be maintained at the same standard as traditional face-to-face encounters for documentation, maintenance, and transmission of the medical record of the

⁵⁹⁴ – Ibid.

⁵⁹⁵– Scott A Edelsten, JD. MPA. Careful. Telemedicine Planning limits costly liability Exposure. Group practice Management, p.1.

telemedicine encounter. Such policies and procedures should address (1) privacy, (2) healthcare personal who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number, and type of transaction, (6) archival and retrieval options, and (7) quality oversight mechanisms.

Policies and procedures should be evaluated periodically for currency and be maintained in an accessible and readily available manner for review. Some states, such as California, have more onerous requirements for posting of such policies and procedures.⁽⁵⁹⁶⁾

Medical Devices Regulation: ⁽⁵⁹⁷⁾

Some telemedicine hardware and software are subject to approval by the Food and Drug Administration (FDA). In July 1996, the FDA's Center for Devices and Radiological Health established guidelines for regulation of telemedicine devices increases, providers should consult with appropriate counsel before marketing new telemedicine technology.

The number of women living in Ireland and Northern Ireland seeking medical TOP through WoW has increased steadily over time.

⁵⁹⁶ – Steven T. Kmucha, MD, JD, FACS. Op. cit. p.12.

⁵⁹⁷ – Scott a Ede/stein. Op. cit. p 68.

In 2010, 548 women performed an online consultation with WoW. By 2015, this number had more than doubled, to 1438. Overall, between January 2010 and December 2015, 5650 women contacted WoW to request medical TOP through the online consultation form. Among the 1636 women to whom mifepristone and misoprostol were shipped between 2010 and 2012, follow-up data were obtained for 1181 representing 72 % follow up. Correction added on 30 May 2017, after first online publication: 1642 has been changed to 1636 in the preceding sentence. Of those with available follow-up data, 1023 (87%) completed TOP. A sensitivity analysis of the characteristics drawn from the consultation form for women who did not completed follow up indicated no meaningful differences compared with those of women for whom follow up was complete. ⁽⁵⁹⁸⁾

The evaluation form and email follow up asked women to share: feeling regarding at-home medical TOP as an option: previous knowledge of medical TOP, difficulty affording the \$70 donation, adequate emotional support-defined as the ability to talk to family and friends and ask them for help, recommendation of at-home medical TOP to others in a similar situation, overall experience of at-home medical TOP-defined as whether or not at-home medical TOP was completed. For each variable, women could select one or more

⁵⁹⁸- ARA, Aiken. R. Gomperts. J. Trussell an international Journal of obstetrics and Gynaecology 2016. www.bjog.org.p1211.

options from a list and/or write a free text response, as many responses as they desired (displayed in Table 2). Women were also invited to share further long-format comments on their experiences with their pregnancy, seeking TOP and at-home medical TOP using online telemedicine. The evaluation form also contained questions assessing resolution of pregnancy and presence of any medical complications, which were not examined in this study.⁽⁵⁹⁹⁾

In Ireland and Northern Ireland, where safe TOP is not legally available through the formal healthcare setting, a diverse range of women access at-home medical TOP through online telemedicine. For most women, their experience is overwhelmingly positive, especially in light of their alternatives. Many faced a pregnancy that they did not want or did not feel they could continue or would otherwise have been forced to remain pregnant at severe cost to their psychological wellbeing. Although online telemedicine TOP provides an important option for women with the fewest financial resources are still more likely to lack social and emotional support during and after at-home TOP. Relatedly, women commonly felt shame and isolation due to the stigma surrounding TOP, engendered by its illegal status and criminalization.⁽⁶⁰⁰⁾

⁵⁹⁹ – ARA. Aiken R. Gomperts, J. Trussell an international Journal of obstetrics and Gynaecology 2016, op. cit. p 1210.

⁶⁰⁰ – ARA, Aiken, R. Gomperts J. Trussell. Op. cit. p. 1213.

Telemedicine in China:

"Perhaps a better solution to China's immediate need for cardiac surgeons is to import these surgeons via cyberspace. Cybersurgery is a method of providing remote surgical expertise by using existing telemedical technology to operate a remote robotic surgical instrument. Although America has thus far other nations. Canada in particular has advanced cybersurgery well beyond the prototypic demonstration stage. In 2004, the Canadian government announced that its cybersurgery operational center was up and running. This center, which is located in Hamilton, Ont., is routinely involved in the intra-operative care of patients located 231 miles away in North Bay, Ont. Thus, from a technologic point of view nothing bars a surgeon located in America from operating on patients located in China.

Conceptually, rather than increase the social demands on its society by ramping up its education system or importing foreign surgeons. China could meet its immediate need for cardiac surgeons by hiring American cyber cardiac surgeons. Such an approach would not place strains on the Chinese society because the use of cybersurgery would; (1) eliminate China's need to educate highly trained specialists whose skill-set would quickly become obsolete, (2) avoid potential social unrest associated with the need to assimilate foreign surgeons, and (3) circumvent the problem of foreign surgeons living in China having to become fluent in Chinese.

Still, whether the demand for cardiac surgeons in China is met through increasing the number of surgeons by physical or telemedical presence, the surgeons will want to be paid. Ideally, underemployed American surgeons would like to maintain their current level of income, which may be problematic at present, in part because the Chinese are a poor people who cannot afford to pay much for needed medical services or to purchase. And even when China does develop a more mature insurance market. China is likely to learn from America's experience that it is necessary to control the wage-incentives given to providers to avoid over utilization".⁽⁶⁰¹⁾

Ohio defines the "practice of medicine" to include the provision of medical services through the use of any communication, including oral, written or electronic communication. In general, regulation specific to telehealth at the state level is limited. However, Ohio has issued some laws and policies around telehealth practice and use (see table below for more information on Ohio telehealth policies).⁽⁶⁰²⁾

Ohio:

- Beginning Jan. 1. 2015, Ohio Medicaid will reimburse for telemedicine services.

⁶⁰¹ – Thomas R. Mclean- international law, Telemedicine & Health insurance: China as a case study. American Journal of Law & Medicine vol. 32, no. 1, 2006, p. 15.

⁶⁰² – Policy brief, looking a head, op. cit. p. 1.

- Under Ohio law, physicians may not prescribe medication for patients they have not personally physically examined. Exceptions include on-call, emergent and similar situations, as well as Telesychiatry.
- Ohio is one of nine states that have an informed consent policy for telemedicine.

Tennessee: ⁽⁶⁰³⁾

- Medicaid does not reimburse for telemedicine (through the state's Department of Mental Health and Substance Abuse Services allows for reimbursement for delivering crisis services via telemedicine).
- A parity law was recently passed that would require health insurers to cover services delivered in person. The law applies to services provided by both in-and out-of-work providers.
- A proposed rule change in Tennessee would mandate in-person physician visits both precede and supplement telemedicine consults.
- Tennessee is one of nine states that requires special telemedicine licensure for physicians.
- Tennessee is one of 26 states that has an informed consent policy for telemedicine.

⁶⁰³ – Helen Gregg, op. cit.

Artificial Intelligence: ⁽⁶⁰⁴⁾

The National Library of Medicine divides telemedicine into three areas: (1) aids to decision making. (2) remote sensing (transmittal of data and educational materials between sites). And (3) collaborative arrangements for real-time management of patients at a distance. Among the "aids to decision making" is artificial intelligence (AI). Students of this subject split AI into "two different categories: one attempts to shed light on the nature of human intelligence by simulating it or components of it, with the eventual aim of replicating it (or even surpassing it), the other systems that exhibit intelligent behavior regardless of their resemblances to human intelligence.

There are several artificial intelligence systems already in use in health care today. Mycin, for example, is an expert algorithmic system used to assist in management of infectious disease. Acute Physiology and Chronic Health Evaluation (APACHE) III helps to manage intensive care unit (ICU) patients. Inputting 27 factors per patient per day, the system claims 95% accuracy in predicting chances of death. Computers and software programs are also used to assist in calculating doses of radiation for patients with prostatic carcinoma, and to generate warning labels for prescription drugs. The National Aeronautics and Space Administration (NASA) is seeking to transfer a device called a general image pattern classifier to the

⁶⁰⁴ - Joseph, P. Mc Menamin, op. cit. pp. 25-26.

private sector for telemedicine applications. Initially designed to permit retrieval of images themselves had been used to categorize slides of white blood cells into two distinct groups using the stored judgments of a practicing pathologist.

Intellectual Property: ⁽⁶⁰⁵⁾

Much of telemedicine technology is subject to restrictions based on intellectual property law. For example, computer software and other original works of authorship "fixed in a tangible medium of expression" are protected by Federal copyright law. Also, equipment used in telemedicine systems may be protected law is highly complex, it is advisable to consult an intellectual property attorney before entering into any contractual or other business relationship involving a telemedicine system.

⁶⁰⁵ - Scott a Edelstien. Op. cit. p.66.

Telemedicine And Insurance

Medicare and Payment:

The lack of Medicare and Medicaid payment for telemedicine services has impeded the advancement of telemedicine. On November 2, 1998, however, HCFA published final rules governing Medicare payment for teleconsultations in health professional shortage areas (HPSAs). For a telemedicine consultation to be covered, the patient must either reside or receive treatment in an HPSA.

Medicare pays the consulting physician fee schedule (80 percent of the Medicare physician fee schedule for nonphysicians), 75 percent of which is to be paid to the referring practitioner. It should be noted that HCFA has stated that this arrangement under the Federal physician self-referral law. HCFA's final rules, published in the November 2, 1998, Federal Register, should be consulted for practitioner eligibility and minimum technology requirements.⁽⁶⁰⁶⁾

Experience in America has demonstrated that controlling physician incentives to avoid under-or over-utilization of healthcare services is difficult. China, however could benefit from American insurers quarter-century experience in the health insurance market. That is, China does not have to re-invent the wheel. Accordingly, it would not be unreasonable to expect that as China searches for

⁶⁰⁶ – Scott a Ede, stein. Op. cit. p.66.

solutions to its health insurance system it would want to partner with U.S. insurers when the timing is right. For their part, U.S. insurers would undoubtedly be happy to enter China's insurance market because of its fantastic growth potential. Partnership between Chinese and American insurers to develop healthcare products would create a win-win situation because of China's knowledge of its own markets and the U.S. insurers' experience in underwriting. In particular, U.S. insurers could provide valuable insight to their Chinese counterparts on how to manage adverse selection and moral hazard, two phenomena that alter the risk of loss. These partnerships would in turn stimulate international telemedicine, because once sufficient numbers of Chinese obtain insurance covering telemedicine, the stage will be set for America to export its medical expertise to a new market.⁽⁶⁰⁷⁾

The Chinese Insurance Market:

For the past two decades, China has experienced unprecedented economic growth, expanding its GDP from \$50 billion in 1978 to \$950 billion in 1999. Yet the average Chinese citizen does not seem to have benefited from this economic explosion. In particular, healthcare in China is prohibitively expensive (when it can be found) and some Chinese literally die in the streets because of lack of access to affordable healthcare. Thus unsurprisingly, many commentators,

⁶⁰⁷ – Thomas R. MCLean, op. cit. p.21.

from both inside and outside of China, acknowledge that what China needs most is a healthcare system that works.

The characteristics of effective healthcare systems for developing nations like China are: (1) equitable access to quality care, (2) affordable health insurance, and (3) financial sustainability. Access to healthcare in China is very inequitable. For example, although 60% of China's population lives in rural regions. Telemedicine, which improves access to care, would help to rectify this misdistribution of resources. Given that a telemedical business can be established with existing technology and minimal capital expenditures. China could likely improve its healthcare system by providing insurance coverage for telemedicine services. Such insurance coverage would stimulate providers to enter the telemedical market, thereby improving access to care in rural China. Of course the devil is in the details. ⁽⁶⁰⁸⁾

Telehealth Liability:

There are many legal and regulatory issues implicated with the use of telehealth, including cross-border licensure, prescribing, credentialing and cybersecurity. One issue discussed less by telehealth stakeholders concerns potential liability exposure a principle concern for any evolving healthcare industry segment.

⁶⁰⁸- Thomas R. Mclean- international law. Telemedicine & Health insurance, op. cit. p.17.

Medical Professional Liability (MPL) is the primary liability exposure for nearly all healthcare providers. Many telehealth skeptics have long argued that the nature of remote or virtual consults would lead to an increased risk for malpractice given the nature of law the health care services are provided. This argument has not been supported by the data. ⁽⁶⁰⁹⁾

⁶⁰⁹ - Arthur J. Gallagher & Co. op. cit. p.2.

Telemedicine And Privacy

Privacy regarding telemedicine:

Some of the demands imposed by the regulation on data protection may compromise the practice of telemedicine.

For instance, the Data Protection Directive is especially demanding in what concerns cross borders data sharing, particularly for countries outside the EU, whereas telemedicine frequently requires this kind of data flow. If the data are transferred outside the European Economic Area (EEA) additional restrictions should be considered and the transmitting entity must ensure that the non-Member State provides an "adequate level of protection" (Article 25 of Data Protection Directive and Article 41 of GDPR). For instance, some data movement may require specific contracts between the European operator and the trans-European one (16) or the implementation of specific guidelines. Because the U.S. is a frequent country of destiny for European data, some guidelines were created in order to facilitate and expedite the process, the Safe Harbour Principles Commission Decision 2000/520/EC (48).

European regime on health data privacy:

Telemedicine involves the circulation of very sensitive data-the patient's health information- which is considered personal information by the European law, thus, the EU imposes particular requirements regarding health data protection.

The Directive 2011/24/EU establishes, in Article 14, a voluntary network for cooperation between the national authorities responsible for e-health in each Member State, but this purpose must take into consideration the remaining European legislation in this domain, namely the Data Protection Directive, the future GDPR and the E-Privacy Directive (7), (16), (48), (49), (50), (51). The aim of these regulations is, on the one hand to allow private data circulation, and on the other hand to adequately protect the data holder.

Personal data are defined as:

Any information relating to an identified or identifiable natural person (data subject), an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity. (Article 2/a of Data Protection Directive).

Or, in a more simplified way, "any information relating to a data subject" (Article 4(2) of GDPR).

In a survey done in 1999, one in five respondents believed that medical information was improperly used. One in six respondents admitted to providing inaccurate information.

The US Secretary of Health and Human Services established rules for electronic data interchange in June 2000. These rules only apply if the healthcare delivered by the practitioner includes a financial or

administrative transaction, eg, electronic submission of a claim form a healthcare provider to a payer. Also, the rules do not apply if the parties are under the same ownership. In order to best protect yourself, be sure to get an informed consent prior to any patient/client consultation.⁽⁶¹⁰⁾

Many states have laws addressing the disclosure of medical records, but there is little consistency among these laws. At the Federal level, HHS published proposed medical records privacy regulations in the November 3, 1999, Federal Register in response to Congress, failure to pass such legislation by the August 21, 1999, deadline set by the Health Insurance.

Portability and Accountability Act of 1996. The proposed regulations would protect individually identifiable electronic health information that is maintained or transmitted by health plans, healthcare providers.

In general, the proposed regulations would preempt less stringent state medical privacy laws. State laws that are more protective, however, are not preempted. Although the proposed regulations do not include a private right of action for individuals they and criminal penalties. The proposed regulations currently are subject to a 60-day

⁶¹⁰ - Ruthe C. Ashley. Op. cit. p1.

comment period with the final regulations to be effective February.
(611)

Confidentiality:

Four types of confidentiality problems have been anticipated in telemedical practice.

1. Improper disclosure- such as leaving visible or at least easily retrievable data on a screen.
2. Unauthorized access- the hacker problem.
3. Identifying individual patients by aggregating data. "Computers linked together make it possible with relative ease to aggregate into a mosaic a large amount of individual data stripped of personal identifiers that will identify a particular individual with high confidence".
4. Data integrity and authenticity. "Preservation of data integrity means preventing improper alteration or deletion of data, while data authenticity requires assurance that information presented as related to a specific patient is not mismatched or forged".⁽⁶¹²⁾

Contract Claims:

⁶¹¹- Scott A. Ede/stein, JD. MPA. Op. cit. p.2.

⁶¹²- Jose p P. Mc Menamin, Does protects liability litigation threaten picture archiving and communication systems and/or Telemedicine? Journal of Digital imaging. Vol. 11, no. 1 (February) 1998, p. 21.

Contract claims against software vendors are usually based on the Uniform Commercial Code (UCC). Plaintiffs suing companies supporting telemedicine could presumably devise theories based on breaches of implied warranties of merchantabilities UCC 82-314, perhaps alleging third-party beneficiary status respecting contracts between software companies, for example, and healthcare providers. (613)

Tort:

A claim in a telemedicine context could be based on negligence, perhaps in reliance on 552 of the Restatement (Second) of Torts: Information Negligently Supplied for the Guidance of Others:

- (1) One who, in the course of his business, profession, or employment ... supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Can a computer manufacturer be held liable based on 552? In defense, it defense, it can argue that it sells machines, not information. A manufacturer of telemedicine devices, such as a digital camera, for example, could offer the same defense, arguing that

⁶¹³ - Joseph, P. Mcmenamin. Op. cit. p.27.

negligence could not be established by transmission of inaccurate data where the camera used met industry standards. ⁽⁶¹⁴⁾

There's good reason to think Judge Pitman is right about the company's chances of success. Teladoc's legal argument hews closely to a 2015 Supreme Court ruling that found the North Carolina Board of Dental Examiners violated antitrust law when it tried to shut down teeth-whitening kiosks under the guise that such services consisted of "the practice of dentistry", and therefore could only be performed by dentists. The Supreme Court ruled that the dental board, because it is controlled by dentist competitors. Any board consisting of a majority of market participants – the Texas Medical Board has 19 members, 12 of whom are physicians – would need to have direct state oversight to guard against this sort of thing, the court ruled. In his majority opinion, Justice Anthony Kennedy wrote that antitrust law "applies to this case with full force, particularly in light of the risks licensing boards dominated by market participants may pose to the free market. ⁽⁶¹⁵⁾

But here in Texas, where we have an infamous shortage of doctors and nurses, telemedicine has hit a snag. New rules promulgated by the Texas Medical Board last year prompted Dallas-based Teladoc, the largest telemedicine firm in the country, to file a federal antitrust

⁶¹⁴ – Joseph, P. Mcmenamin, op. cit. p. 27.

⁶¹⁵ – John Daniel David on October, op. cit. p. 4.

lawsuit against the board. Specifically, the medical board's new rules (PDF), approved in April 2015 but blocked by a federal judge's preliminary injunction just days before they were set to take effect, stipulate how physicians in Texas can establish a "doctor-patient relationship" with new patients before engaging in telemedicine. A patient must either visit the doctor in person or meet "face-to-face" over video conference. But the video conference must be at an approved medical site like a hospital, clinic, or a fire station, and there must be a "patient site presenter" on hand, like a nurse or a physician's assistant. In other words, you can't just turn on your computer at home, login to a telemedicine app and be connected with a doctor. Put another way, in Texas you have to go a medical clinic to be seen by a doctor, even if the doctor isn't there. ⁽⁶¹⁶⁾

⁶¹⁶- John Daniel Davidson October, op. cit. p.3.