

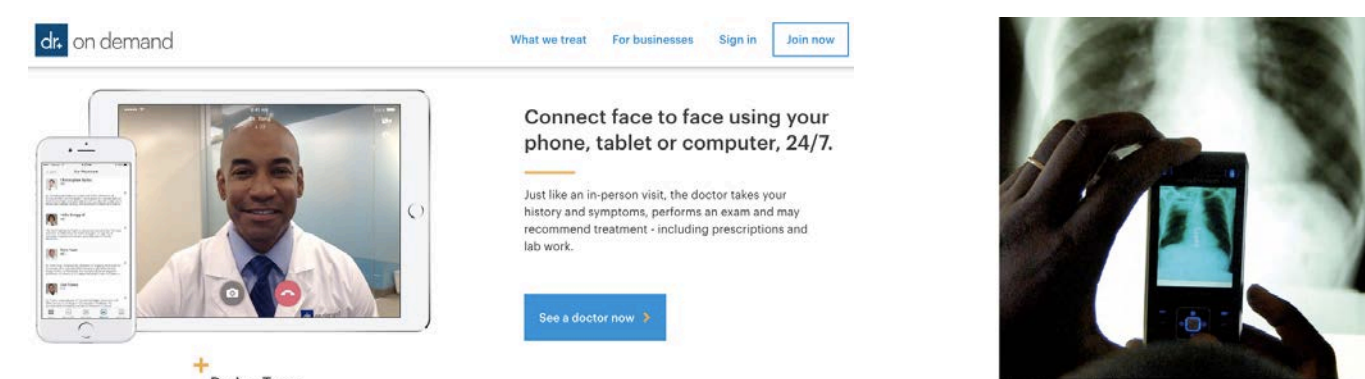
How the European Union Is Embracing Cross-border Telemedicine and What the U.S. State Medical Boards Can Learn From It

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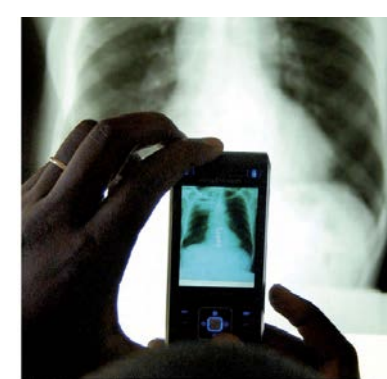
BACKGROUND

Despite the fact that there have been many advances in the field of telemedicine, the United States (U.S.) state and federal laws have not kept pace with these technological advancements and may operate as a barrier to growth in the field of telemedicine. On the other hand, the European Union (EU) has developed a robust legal framework for the practice of telemedicine. Based on the 2015 EU Guidelines, by 2020, a French physician may be able to see a German patient online and have instant access to the patient's medical record, automatically translated into the French language. The EU has prioritized the creation of a legal framework that fully supports cross-border telemedicine.

What Does Telemedicine Mean for Patients?



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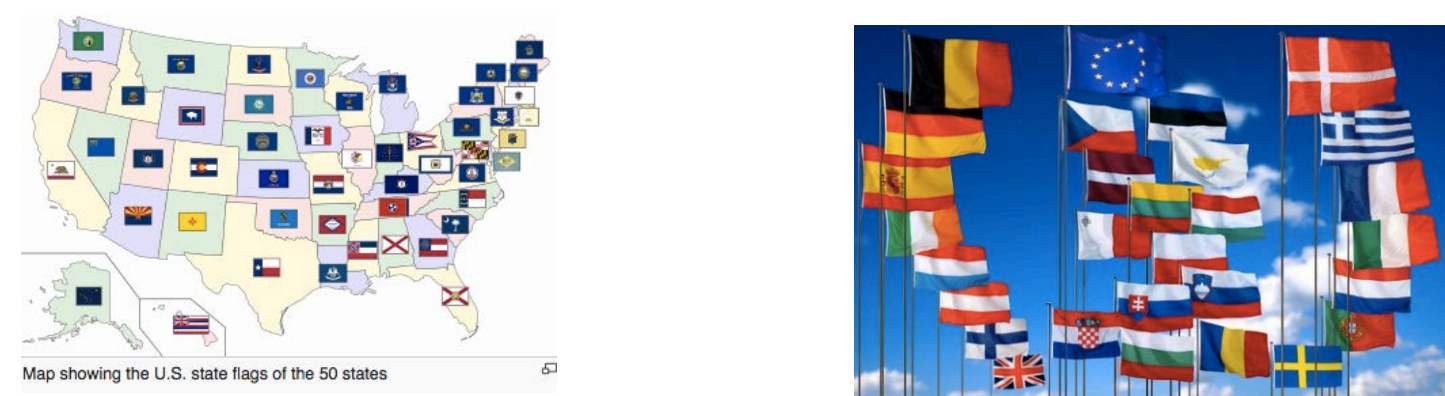
WHO Telemedicine 2010

- Patients may be able to avoid driving to a hospital
- Patients in rural areas can receive services
- Patients may have greater selection of providers
- Patients can check the price before receiving care

METHODS & OBJECTIVES

The aim of this research project is to evaluate what elements of the EU legal experience could be used to support efforts to better align telemedicine law with the practice of telemedicine in the U.S.

Why Compare Europe and the US?



The comparison of European to American telemedicine law is appropriate for several reasons. The U.S. has a federal legal system with 50 independent states that traditionally controlled healthcare within the borders of each state. Similarly, while the EU has only recently created a single economic market, healthcare used to be controlled by each of the 28 member nations.

US AND EUROPE TELEMEDICINE LAW & REGULATIONS

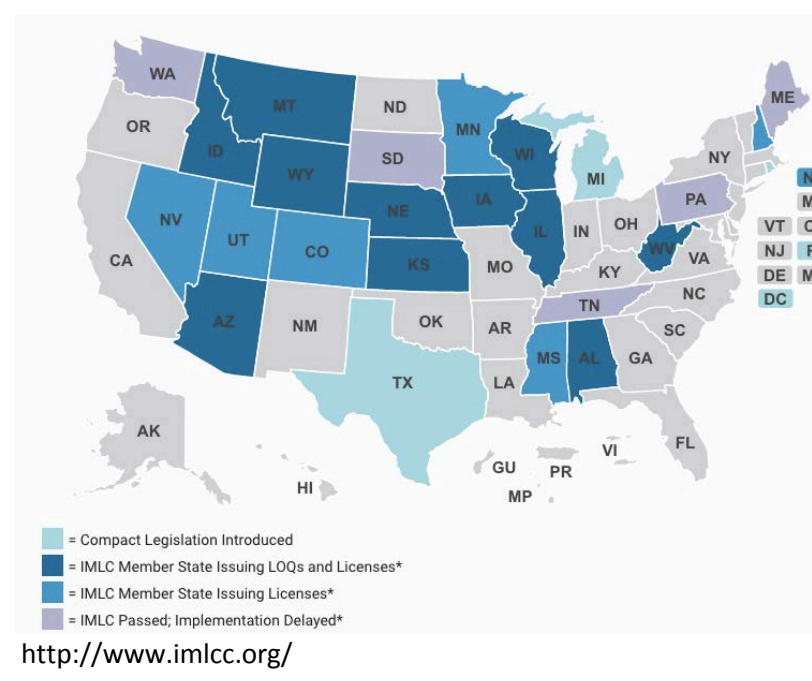
UNITED STATES	EUROPEAN COMMISSION
Federation of State Medical Boards (FSMB) recommends states to have physicians first establish a physician-patient relationship and be licensed at the location of the patient.	1996
The Affordable Care Act signed into law by President Obama (9/23/2010)	2000: The European Commission (EC) issues E-Commerce Directive 2000/31/EC that specified that a healthcare professional practicing telemedicine to be licensed only in the nation where the service is rendered (8/8/2000)
FSMB holds a symposium to address key issues in the growth and expansion of telemedicine with national health experts and policy makers (2/23/2011)	2004: The First Action Plan on eHealth adopted by the European Commission to create a framework to support eHealth (2004)
FSMB explores the concept of interstate compact for physician licensure to increase efficiency in the licensing of physicians who practice in multiple states (4/23/2013)	2010: EC November 4 2010 Citizens' Summary on Better Health Treatment for Travelers and Expats in EU: Commission Recommendation on Cross-border Interoperability of Electronic Health Record Systems. Citizens requested EC to try to achieve European eHealth interoperability by the end of the year 2015.
FSMB released a draft of the "Interstate Medical Licensure Compact" for adoption by state legislatures (7/25/2014)	2011: Cross Border Directive 2011/24/EU specifies that EU patients have a right to receive medical treatment in other member states (3/9/2011)
Same joins FSMB Compact as 22nd state (June 24, 2017)	2011: First Meeting of the eHealth Network of EC took place in Denmark, Copenhagen, to achieve member nation cooperation for achieving the Patients' Right in relation to cross-border healthcare. Annual meetings to follow achieve interoperability of semantics and technology, set standards for identification and authentication, and legal issues regarding telemedicine. (5/8/2011)
The 21st Century Cure Act passed on 2016 requires interoperability of EHR and penalizes data blocking (December 2016)	2012: eHealth Action Plan 2012-2020: a road map for achieving cross-border eHealth in Europe released by eHealth Network, Brussels (5/12/2012)
S. 870 CHRONIC Care Act of 2017 was introduced to Senate (currently pending) in order to expand Medicare coverage for telemonitoring and reduce Medicare cost (4/6/2017)	2012: Discussion paper on Semantic and Technical Interoperability released to eHealth Network: recommends cooperation between nations to achieve legal interoperability, semantic interoperability, and technical interoperability. (10/22/2012)
	2013: Concept of standing coordination groups to concentrate on semantic and technical interoperability issues introduced at the 3rd annual eHealth Network meeting (5/14/2013)
	2013: Guidelines on Minimum/Non-Exhaustive Patient Summary Dataset for Electronic Exchange in Accordance with the Cross-Border Directive 2011/24/EU released at eHealth Network meeting. The same meeting also presented a study regarding existing code systems (11/19/2013)
	2014: European Commission releases a final report on an overview of the national laws on electronic health records in the EU member states and their interaction with the provision of cross-border eHealth Services (7/23/2014)
	2015: 7th Annual eHealth Network meeting: Legal Subgroup is instructed to resolve conflicts created by different liability standards among member states (Meeting minutes, 5/12/2015)
	2016: The Guideline on the Electronic Exchange of Health Data under Cross-Border Directive 2011/24/EU released at the 10th eHealth Network at Brussels (11/21/2016). The Draft Legal Agreement on Cross-Border Exchange of Health Data, to be adopted by member nations on a voluntary basis, released during the 10th eHealth Network meeting (11/21/2016). The Draft Legal Agreement sets out data interoperability standards, liability standards, and roadmap for medical term translation for medical records in different languages.
	2017: Technical problems that arose during eID use in 14 nations discussed during the 6th meeting of the eHealth DSI Member State Expert Group (3/6/2017)

FINDINGS

Physicians in the United States face many legal and technical barriers to providing efficient telemedicine care to patients in other states. Physicians may have to seek licensure in other states, and may not have the ability to access medical records. Physicians may also encounter difficulties in obtaining insurance payments.

The EU regulatory framework intends to facilitate the development of cross-border medical services, i.e. services which are provided by a physician in one country to a patient in another country, and aspires to provide highly efficient care even in unscheduled clinical encounters, in which medical records were not made available in advance.

Interstate Medical Licensure Compact



- Expedited state medical licensure application process.
- Requires an unrestricted license in at least one state.
- Requires payment of appropriate fees and waiting time for approval by each state medical boards.

Not a Great Solution for True Interstate Telemedicine!

Reimbursement in US

- Insurance companies pay for health costs.
- Some states adopted telemedicine parity law to force insurance companies to cover telemedicine care.
- Different coverage of specialties exist.
- Initial face-to-face visit required in some states.

	United States	Europe
Medical License Requirements for Crossborder Telemedicine	Most states require a medical license for both the state where patient is located and the state where physician is practicing Interstate Medical Licensure Compact: Expedited multistate license process, available in 12 states	License required in nation where physician is located without regard to patient location EU eCommerce Directive of 2000 established that a EU physician is required to be licensed only in the member nation from which he provides telemedicine services, without regard to the location where the services are received.
License Requirement for International Telemedicine outside of EU or US	Many U.S. state medical boards do not have a clear opinion regarding physicians' remote medical services to patients outside of the United States.	"Country-of-Origin" Doctrine based on EU eCommerce Directive of 2000: License is required in nation where physician is located without regard to the location where the services are received.
Reimbursement for Telemedicine Consultation	Some form of telemedicine parity law has been adopted by at least 31 states. As each state has adopted different telemedicine parity laws, there is no uniform reimbursement standard across state lines. Federal Medicare Telehealth Parity Act (HR 2948, pending)	Directive 2011/24/EU: EU patients have a right to receive medical treatment in member nations, and be reimbursed under given circumstances. Directive 2011/24/EU Article 7: Member nations can require prior authorization for reimbursement of telemedicine services.
Digitization of Health Records, and Use of EMRs	EMR use is increasing after ACA Some EMRs allow patient access	National EMRs adopted in many countries Many national EMRs allow patient access (e.g. Denmark and Spain) and others are working towards providing access.
Legislation or Standards for Interoperability	The 21st Century Cure Act passed in 2016 requires interoperability of EHR and penalizes data blocking. Specifics of possible interoperability standards are being investigated by various organizations.	2013 Guideline for Cross-Border Directive 2011/24/EU: European Commission eHealth Network established a minimum/non-exhaustive patient summary dataset for electronic data exchange. 2014 Guideline for Directive 2011/24/EU: European Commission eHealth Network established an ePrescription dataset for electronic exchange. EC eHealth Network is working together to progressively achieve interoperability across EHRs of member nations (EC eHealth OECD study 11/2016)

Medical Licensure in Europe

- A physician needs to be licensed only in the nation from which he is rendering medical care, not in the nation where the service is received by patient.
- European Commission E-Commerce Directive of 2000 created a Digital Single Market within European Union member nations.



https://en.wikipedia.org/wiki/European_Union

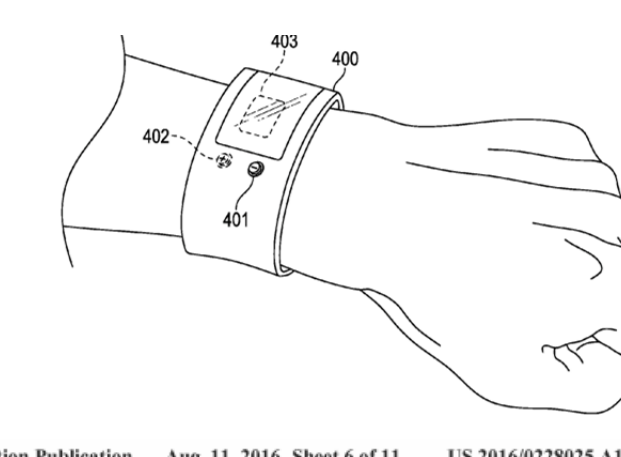
EMR Interoperability in Europe



Guidelines on Minimum/Non-Exhaustive Patient Summary Dataset, adopted by eHealth Network on November 19, 2013.

- Goal by 2020:
 - Patients can see physicians abroad in person or via telemedicine
 - Real-time translation of patient summaries
 - Cross-border access to medical records
- Leaders and experts of member nations regularly meet to achieve data interoperability.

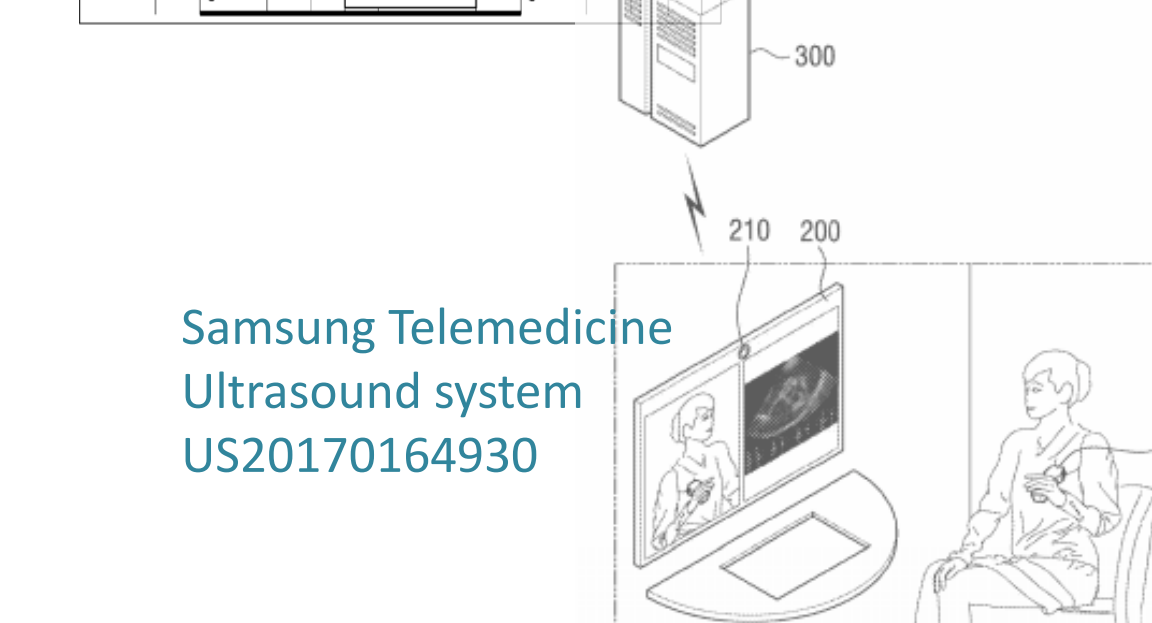
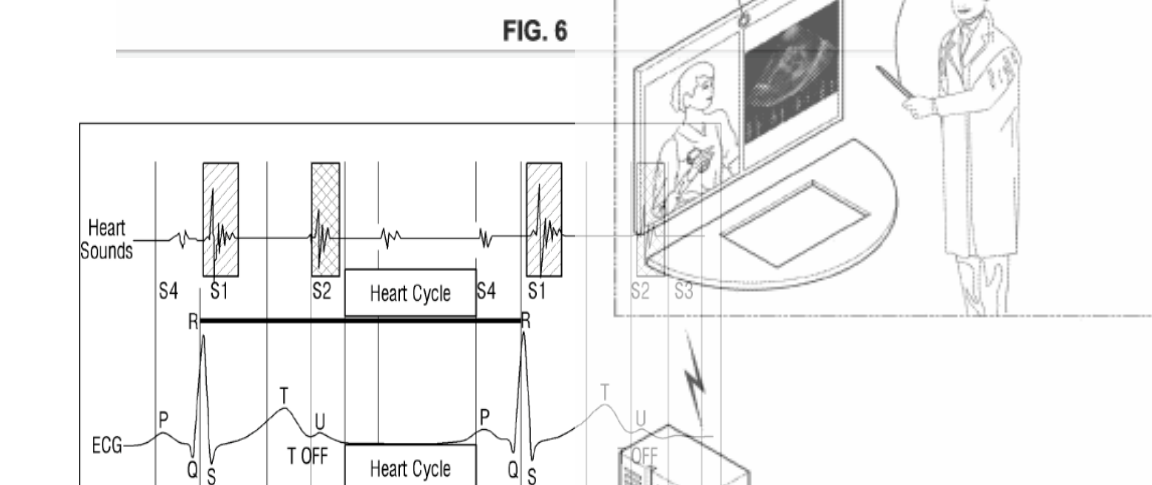
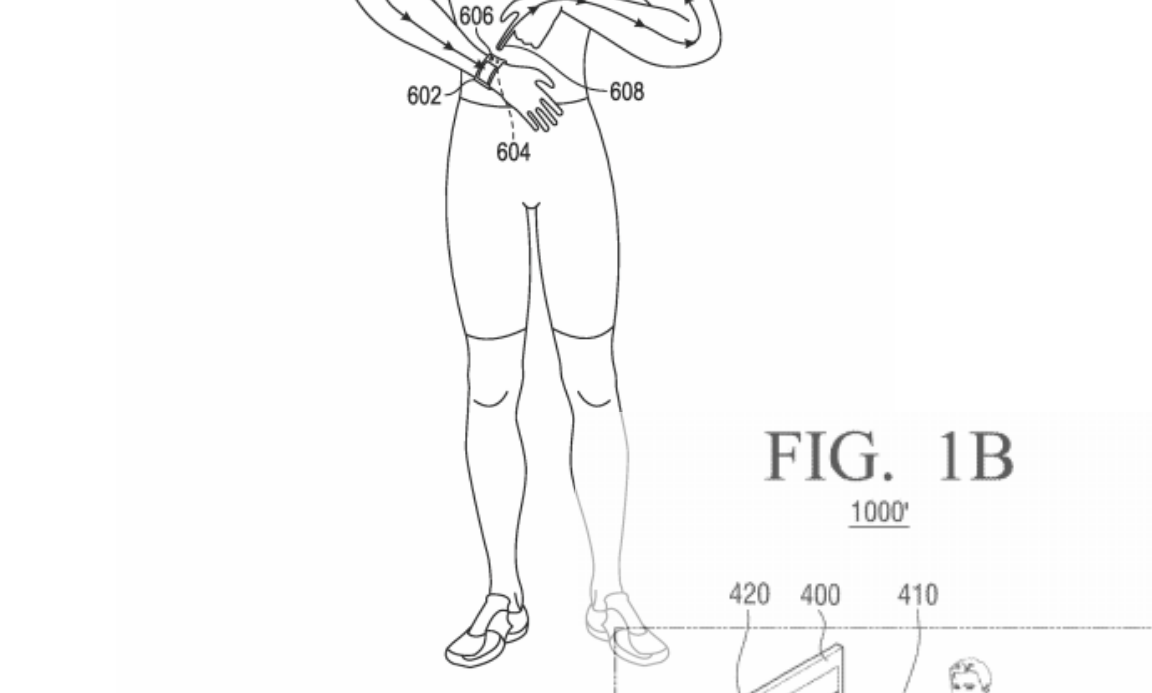
Future of Telemedicine



Patent Application Publication Aug. 11, 2016: Sheet 6 of 11 US 2016/0228025 A1



Apple's Wearable ECG US 2016/0228025



Samsung Telemedicine Ultrasound system US20170164930

CONCLUSION

U.S. medical licensure requirements for telemedicine practice are comparable to EU regulations before 2000. Furthermore, U.S. telemedicine reimbursement regulations arbitrarily differ across state borders, and electronic medical record systems from various companies do not communicate properly with each other.

We recommend that the state medical boards allow physicians licensed in one state to provide telemedicine services to patients in other states. Furthermore, we recommend collaboration among the state medical boards, industry leaders, and state legislatures to come up with uniform telemedicine reimbursement regulations and to design a uniform electronic medical record inter-operability standard to allow the U.S. telemedicine industry to keep abreast of the global developments in telemedicine.

Key Recommendations

- Licensure requirements should be liberalized to allow a licensed physician to practice telemedicine without regard to patient location.
- State legislatures should work together to create a uniform telemedicine parity law.
- Government and industry leaders need to work together to create one interoperability standard for all existing EMRs.

REFERENCES

1. Commission of the European Communities, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Telemedicine for the Benefit of Patients, Healthcare Systems and Society. Brussels, 4.11.2008. COM(2008)639 final.
2. eHealth Network, Guideline on an Organisational Framework for eHealth National Contact Point, adopted by consensus by the eHealth Network, Brussels, 23 November 2015.
3. Raposo VL. GMS health technology assessment: Telemedicine: The legal framework (or the lack of it) in Europe. GMS Health Technology Assessment 2016, Vol. 12, ISSN 1861-8863.
4. Thomas L. and Capistand G., 50 State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure, American Telemedicine Association, February 2017.
5. Prognosis, The Physician's Guide to Telemedicine in 2017. Bizmatrics. Inc.