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Global Telehealth: Complying With the FCPA, Privacy and Security Laws, Fraud and Abuse Laws

Overcoming Regulatory Hurdles When Providing Telemedicine Services Internationally

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Global Telehealth

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Agenda

- Telehealth Models
- Fraud & Abuse / Foreign Corrupt Practices Act ("FCPA")
- Privacy and Security
- Medical Licensure, Credentialing, and Privileging
- Professional / Product Liability
- Contracting Considerations & Dispute Resolution
- Questions

Local vs Global – A Context for Telemedicine Models[1]

- Terminology
  - Global Health telemedicine focuses on Information and Communication Technologies (ICT) that affect organizations, management models, culture and medical care services. ICT is an umbrella term that includes any communication device or application: radio, television, cellular phones, computer and network hardware and software, satellite systems and so on, as well as the various services and applications associated with them, such as videoconferencing and distance learning. ICTs are often spoken of in a particular context, such as ICTs in education, health care, or libraries. The term is somewhat more common outside of the United States.
  - Telehealth serves as a communication tool within the broader IT space representing the interactive, electronic exchange of information for the purpose of diagnosis, intervention, or ongoing care management between a patient and/or health care providers situated remotely
  - WHO defines telemedicine as "the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities."

[1] See "Framework for Implementation of Telemedicine Services" PAHO/WHO eHealth Program; www.paho.org/ict4health

The Global Telehealth (R)evolution

- In May 2005, health ministers of the 192 WHO countries approved the eHealth Resolution recognizing the contribution of incorporating ICTs in health and health system management.
- eHealth was described as the "cost effective and secure use of ICT in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research."[2]
- In April 2004, the EU had established a Plan of Action for the creation of the "European eHealth Area" stating that "…eHealth can improve access and boost the quality and effectiveness of the services offered." [3]
- eHealth is now described by those countries that subscribe to it as "the application of the Internet and other related technologies in the health care sector for improving access, efficiency, efficacy and quality of clinical and corporate processes used by health care organizations, physicians, patients and consumers in an effort to improve the health status of patients.

[2] Ibid.

[3] See EU eHealth Action Plan 2004 - 2010

Telemedicine Applications

- Common areas for use of telemedicine occur in acute care, primary care and skilled nursing care. Other areas include home-based care.
- Specific applications of telemedicine include[4] :
  - Diagnostic x-ray and other images- (tele-radiology)
  - Clinical laboratory, including records and history (tele-pathology)
  - Dermatology assisted by videoconference or image transmission (tele-dermatology)
  - Assisting psychiatric patients via videoconferences and chats (tele-psychiatry)
  - Treatment of cardiovascular disorders (tele-cardiology)
  - Visualizing ocular and retinal diseases of the eye (tele -ophthalmology), and
  - Use of telemedicine resources coupled with virtual reality, robotics and artificial intelligence [AI] to support, monitor or perform procedures.

[4] In the US, the top specialty applications include stroke, psychiatry, neurology, radiology and pediatrics. (see REACH Health Survey "2017 US Telemedicine Industry Benchmarks at : http://reachhealth.com/wp-content/uploads/2017-US-Telemedicine-Industry-Benchmark-Survey-REACH-Health.pdf]

Components of eHealth

- Health informatics – the integration of health information networks and distributed systems of electronic medical records and associated services for gathering, analyzing and distributing health-related information.
- Telehealth/telemedicine – direct or indirect interaction with other health care providers, patients or other persons.[5]
- E-learning – the use of ICT's for educating providers and citizens.
- Electronic commerce – associated with business aspects such as insurance and reimbursement.

[5] Per National Academy of Science, Telemedicine usually involves direct patient care; telehealth has a broader definition. (see http://www.iom.edu)

Key Factors In Developing Telemedicine Services

- Legal, regulatory and security issues (See co-presentations)
- Technological and infrastructure issues
- Human resource issues and
- Financial issues

Telemedicine Models and Applications

- Patient-to-Provider
  - E-Visits
  - Wearables
  - Secure Messaging

Telehealth Modalities

Real-time virtual visits

Remote patient monitoring

Asynchronous store and forward

- Provider-to-Provider
  - E-Consults
  - Implantables
  - Second opinion consults

Telehealth is a tool, and not a self-contained strategy. It is an application that can have different goals and outcomes depending on its application and use. (The Advisory Board; 2018)

Reconciling Inbound and Outbound Telemedicine Issues in a Global System

- Examples of Outbound professional services
  - US doctor consulting with foreign doctor and/or patient
  - US hospital providing specialty consultation/monitoring of US facility operating in foreign country
  - Self-funded US employer seeking to make available to its employees working out of the country access to contracted telemedicine providers
- Examples of Inbound professional services
  - US company contracts with foreign doctors to provide diagnostic interpretations for US patients (e.g. Nighthawk Model)
  - US provider seeks consultation from foreign doctor on a particular clinical matter

Payment Issues

- US Payment Challenges – Mostly fee-for-service private system
  - multiple payor healthcare system operating under different reimbursement rules
  - different states have different requirements regarding provider eligibility to provide health care services
  - federal government programs vary in coverage and terms of payment
- Foreign Payment Challenges – Mostly publicly funded system
  - National Health System model has inherent cost constraints that will require demonstration of a ROI
  - Some countries permit private pay; others do not.

Key Questions to Ask Related to Telemedicine Services Reimbursement

- Where is the origination site located vs the distant site where services are being provided?
- Who is providing the services and is telemedicine included in their scope of practice?
- What services are being provided? Sometimes the coverage of particular services is determined by “where” the services are provided.
- How is the technology used? Payers often restrict modes of communication and have not yet aligned their reimbursement to the three primary modes used in telemedicine – real time, store-and-forward /asynchronous and remote patient monitoring.

Consider alternative sources of funding for services from government sources (grants), charities, self-pay or value-based payment.

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Domestic Fraud and Abuse

- Federal fraud and abuse laws (Stark, AKS)
  - Apply if payments by federal health care programs are involved
  - It is highly unlikely that such programs would be implicated in global telehealth models
- Some states have “all-payor” fraud and abuse laws that can apply

FCPA Scope and Requirements

- Anti-bribery provisions: Apply to US persons, US entities, and entities issuing securities publicly traded in US markets
  - Unlawful to offer or give anything of value to foreign government officials to wrongfully influence them to assist, in their official capacity, in obtaining or retaining business (known as the "business purpose test")
  - Attempts are prohibited—they needn't succeed
- Accounting provisions: Apply to entities issuing securities publicly traded in US markets
  - Require maintenance of books and records of transactions, as well as a system of internal accounting controls
- Joint SEC and DOJ enforcement

FCPA Penalties

- Criminal Penalties (DOJ)
  - Anti-bribery provisions: for **Entities**, up to $2M; for **Individuals**, up to $250k and 5 years' imprisonment
  - Accounting provisions: for **Entities**, up to $25M; for **Individuals**, up to $5M and 20 years' imprisonment
  - Alternative Fines Act: Fine may be up to twice the benefit that the defendant obtained by making the corrupt payment
- Civil Monetary Penalties (DOJ and SEC)
  - Anti-bribery provisions: up to $16k
  - Accounting provisions: up to the greater of (a) the gross pecuniary gain and (b) a specified dollar limitation (up to $725k for **Entities** and $150k for **Individuals**)
- Suspension or debarment from contracting with the federal government (including Medicare and Medicaid)

FCPA: Who is a Foreign Official?

- Broad definition includes low-ranking employees, high-ranking officials, and intermediaries:
  - "any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization" 15 U.S.C. § 78dd-1(f)(1)(A)
  - May include officers and employees of state-owned or state-controlled entities
- Fact-specific analysis to determine if the recipient is a Foreign Official

FCPA: Affirmative Defenses

- Local Law
  - Payment was lawful under the written laws and regulations of the foreign country
  - Lack of enforcement or local custom are not sufficient
- Reasonable and *Bona Fide* Business Expenditure
  - Payment was part of demonstrating a product or performing a contractual obligation
  - Includes reasonable travel and lodging expenses
  - Does not include trips that are primarily for personal entertainment purposes

FCPA: Global Telehealth Implications

- Healthcare delivery and healthcare financing often are state-based in jurisdictions around the world
  - Counterparty organizations may be governments, or instrumentalities
  - Individuals involved in projects may be government officers or employees
- Some models of global telehealth may require local licensure or permitting

FCPA: Proactive Steps

- Understand your counterparty
  - Is the organization a government or instrumentality?
  - What is the status of individuals who are involved?
- Understand the official, written laws and procedures of the foreign country—and where they may differ from custom
- US fraud and abuse laws may not apply, but they provide good, familiar guidelines
  - Consider whether expenses are reasonable
  - Consider whether expenses are *bona fide*
  - Keep accurate and complete records of all expenses

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US Privacy Law

- 4th Amendment
- *Griswold v. Connecticut,* 381 U.S. 479 (1965)
- HIPAA, Pub. L. No. 104-191, 110 Stat. 1936
- HITECH, s. 13402, Pub. L. No. 111-5, 123 Stat 115
- COPPA, 15 U.S.C. 6501–6505, 16 CFR Part 312
- FTC's Fair Information Practice Principles
- State medical records privacy laws
  - California Confidentiality of Medical Information Act, e.g.
    - Authorization required for disclosure of data re: STDs (must report + AIDS tests), SUD tx, outpatient psychotherapy notes
    - Private right of action (unlike HIPAA)

International Authorities

- **UN** Universal Declaration of Human Rights, Art. 12: ”[E]veryone has the right to the protection of the law" to prevent "arbitrary interference with his privacy.” (1949)
- GATS, Art. XVI(c)(ii): **WTO** members may adopt measures for "protection of privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts” (1995)
  - May not apply arbitrarily or in unjustifiably discriminatory manner.

WORLD TRADE ORGANIZATION

International Authorities, 2

- **WHO**, Global Observatory for Ehealth (2005)
  - Dedicated to the study of eHealth: the use of information and communication tech (ICT) for health
  - Evidence-based guidance to countries and institutions
  - Atlas of eHealth: practices of 125 countries (2009, 2015)
- **OECD** Guidelines on the Protection of Privacy and Transborder Flows of Personal Data (1980, 2013)
  - Limitation of data collected
  - Maintenance of data quality
  - Specification of the collection purpose
  - Limitation of data use to that specified purpose
  - Adequate security
  - Transparency
  - Individual access to and control of data collected
  - Accountability

EU Privacy Law

- Council of Europe: Art. 8, Eur. Convention for Protection of Human Rights [and Fundamental Freedoms] (1950): ”[E]veryone has the right to respect for his private and family life, his home and his correspondence.”
- CoE’s Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981)
  - 1st binding international agreement of its kind
  - Countries must "respect...rights and fundamental freedoms, and in particular [everyone’s] right to privacy"
  - Fair information collection for a specific purpose
  - Limitation to the purpose specified
  - Accuracy
  - Storage for no longer than necessary for the purpose
  - Accessibility by the subject
  - Reasonable security

EU Data Protection Directive
95/46/EC (1995), now replaced by GDPR

- Controller: "the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data..."
  - Must provide detailed information whenever it uses any individually identifiable information
  - Controller outside EU: applicable law is that of Member State where processing took place
- Right of erasure
  - Incomplete, inaccurate, or improperly stored data
- "Profiling"-using any personal info for marketing-prohibited
- Enforcement: required, but member countries control

Further EU Privacy Evolution

- Eur. Parliament and Council: **E-Privacy Directive** (2002)
  - Promoted access to information across various countries
  - Must report personal data breaches to national authorities
- Data Directive's Article 29 Working Party "**EHR Report**" (2007). Data controller must:
  - Limit data use to purpose they were collected for ("purpose principle")
  - Ensure data quality (relevance, accuracy)
  - Limit data retention (and not further process the data)
  - Provide individuals with data collection information and access to it
    - Rights of correction
  - Provide appropriate data security measures
  - **GDPR**: replaced Art. 29 WP w/Eur. Data Protection Board

GDPR 5/18 : Replaced Earlier Directives

- Goals: Uniformity, harmonization
  - Balance: Info services' trustworthiness v. protecting rights
  - Incentivize non-EU businesses to build EU offices
  - Keep regulations vague enough to allow for change
- Opt-out is out:
  - **Opt-in** consent required; can withdraw at any time
  - Not given if there's "a clear imbalance between the data subject and the controller," especially public authorities
  - "Clear and plain language" in documents
- BINDING. Enforcement
  - **€20M or 4%** of worldwide turnover in previous year
    - 1/21: Google €50M fine: how data used for personal ads
  - Litigation

GDPR, 2

- Coverage: EU person or non-EU person in EU
- Application: all companies doing business in Europe
  - Non-profits
  - Marketing activity over **internet**
- Application to non-EU entities
  - Process personal data: do anything with or to data
  - Monitor behavior of data subjects within Europe OR
  - Offer goods or services to individuals in EU
- No safe harbor for anonymization (de-identified data)
- Breach: 72 h to inform, unless unlikely to affect subject's rights (HIPAA: 60 d)

GDPR Rules of Data Processing

- Can process data under certain circumstances only:
  - Subject's consent
    - Freely given, specific, informed, unambiguous. **OPT IN**
  - To protect interests of a subject unable to consent
  - Duties under employment, CBA, or social security
  - Litigation, legal process
  - Substantial public interest proportional to aims and with safeguards
  - Health care and public health
  - Subject makes data public (unlike HIPAA)

GDPR: Unique Rights

- **Right to be forgotten**: erase personal data “w/o undue delay”
  - Google must remove data re: convicted autistic Finnish murderer
  - Exceptions:
    - Exercise of "freedom of expression”
    - Public health interest; "historical, statistical, and scientific research”
    - Retention by the EU or member state under state law
- Right to **restrict** data processing: may process with subject’s ok only; can bar further dissemination, especially personal data subject made available as a child
- Right to data **portability**: transfer from 1 organization to another or to subject
- **Subject access**: broader rights than in US
  - Respond in 30 d, not 40
  - No fee for one copy
  - Disclose: purpose, categories, recipients, rectification or erasure, eg.

Google Spain SL v. Agencia Espanola de Proteccion de Datos

- Spanish newspaper could publish story on plaintiff's property up for auction for Social Security debts.
- Under Art. 12, GDPR, Google had to take down
  - Case C-131/12, *Google Spain SL v. Agencia Española de Proteccion de Datos*, (AEPD), 2013 ECLI:EU:C:2014:616 (May 13, 2014)
- When operating within the EU, US entities bound
- Cf., **California** Consumer Privacy Act of 2018

EU Approach, Summary

- Patient control of health information
  - Even when info collection not based on consent
  - Right to prevent sharing, even with other HCPs
  - Actual patient understanding of info collection, sharing
- EU: opt-in (v. US opt-out)
  - Cannot force anyone to be part of an EHR
- Security: organizational, process and technical protection; safeguards for authorized access
  - Less detailed than HIPAA
- AI: EU bars ? processing data in ways different from initial collection purposes; data minimalization, storage limitations

Privacy Shield, 2016

- Replaced Safe Harbor (1995)
- Agreement separate from GDPR, but framework similar
- Aim: ensure US companies comply with EU privacy law
- Participants: U.S. and EU businesses; European citizens, Data Protection Authorities (DPAs)
  - Commerce collaborates with EU DPAs to see that EU and U.S. agree on which companies are compliant
- Voluntary, but US company can transit data re EU citizen only if a member
  - Once an entity commits to complying with the Privacy Shield, the commitment becomes enforceable under U.S. law (FTC)
    - Then, free transfer of data between U.S. and EU business

China Data Privacy Standard
GB/T 35273-2017 (5/18)

- Protects "sensitive personal info": any personal data that would harm persons, property, reputation, or health if lost or abused
  - E.g., nat'l ID card numbers, login credentials, banking and credit details, one's location, one's real estate holdings, info re: a minor
- Requires advance consent to collection of personal info and its subsequent use
  - Further consents for any activity exceeding original scope
  - Exceptions: troubleshooting products and services; news reporting
- Privacy notices: Standard does not identify info that can be omitted if individual has access to it from other sources
- For personal info processing entities: More specific security testing and procedure requirements

Steps to Consider

- Determine if in compliance, at home and abroad
- Document legal basis for processing
- Check security measures
- Update breach response plan
- Data protection officer
- Update P&P including for kids
  - Utilize any privilege protection law may make available

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Limiting Liability Through Regulation

- Licensure – What licenses are required for the delivery of care? Which professionals use the technology to deliver care?
  - Assuring appropriate licensure in the state/country of patient origination is important to managing risk.
  - In many countries, healthcare providers are not permitted to provide healthcare services unless licensed/registered in the country or local jurisdiction where they are providing services.
  - Mutual recognition of standards (EU) allows physicians registered in one EU member country to be able to provide virtual health care services to patients in other EU countries.
- Standard of Care – Does the service meet the applicable standard of care?
  - Most countries have standards for regulating "online" doctors
  - In England, the Care Quality Commission (CQC) is responsible for regulating physicians and in March of 2017, published a "Clarification of Regulatory Methodology" which sets specific regulatory standards for providers of primary medical services online and requires them to register.

See: "Online Doctor Standards" http://www.cqc.org.uk

Medical Licensure

- Foreign jurisdictions may have licensure requirements for remote telehealth providers
- Different telehealth models may implicate different licensure requirements
- Become familiar with the licensing requirements applicable to your desired telehealth model in your target jurisdiction
- The following slides will provide an overview of licensure requirements for the European Union, China, and India

Licensure: European Union

EU-Based Provider to EU-Based Provider/Patient

- Country-of-Origin Principle: A telehealth provider in an EU member state must comply only with the licensure requirements of his or her EU member state when providing services to patients or providers located in other EU member states.
- EU states must reimburse patients who receive remote care from a provider in a different member state as they would reimburse domestic telehealth services
- EU providers must charge patients in other member states the same rates they charge domestic telehealth patients

Licensure: European Union (cont'd)

Non-EU-Based Provider to EU-Based Provider/Patient

- The provider must comply with each target EU member state's licensure requirements
- This may be onerous for U.S.-based providers looking to provide remote services in multiple EU member states
- There is no obligation for member states to reimburse patients who receive remote care from a non-EU provider at the same rate as they would reimburse domestic telehealth services

Licensure: China

- On September 14, 2018, the Chinese National Health Commission ("NHC") promulgated a set of new rules to regulate domestic telehealth activities ("New Rules")
- The New Rules allow the following types of internet-based healthcare services:
  - Remote physician-to-physician consultations
  - Internet-based diagnosis and treatment
  - Internet hospitals
- Whether and to what extent Chinese health authorities will apply the New Rules mutatis mutandis to cross-border telehealth remains an open question

Licensure: China (cont'd)

- Remote physician-to-physician consultations under the New Rules cover two major scenarios:
  - One medical institution renders remote healthcare services at the request of another to assist with patient diagnosis and treatment through information technology
  - A medical institution or a third party establishes a telehealth platform, and another medical institution registers on this platform as a user to render remote healthcare services at the request of the inviting medical institution or through matching services by the third party
- A medical institution does not need advance approval to facilitate remote physician-to-physician consultations, unless it intends to establish a telehealth platform accessible by multiple medical institutions

Licensure: China (cont'd)

- Outbound transmission of health and medical data under China's Cybersecurity Law
  - Operators of Critical Information Infrastructure ("CII") store "citizens' personal information and important data" collected or generated in the course of operations within China (hospitals are likely CII Operators)
  - Health and medical data should be stored onshore. If outbound data transmission is necessary for operational reasons, a security assessment must be conducted by designated agencies, unless otherwise specified by laws and regulations
- Cross-border data transfers include circumstances where network operators provide personal information and important data collected or generated in China to foreign entities, organizations, or individuals, directly or by other means
- Prohibition on unauthorized transfer of health and medical data that could jeopardize national, social or public interest

Licensure: India

- No laws or regulations specifically address telehealth licensure
- Licensure and registration with the Medical Council of India is required to practice medicine
  - Not much statutory precision regarding what constitutes the practice of medicine
  - Likely includes provider-to-provider consultations
- Providers licensed in other jurisdictions may apply for a temporary permission to practice

Provider Credentialing: A Compliance and Risk Management Tool

- Health Systems and organizations that rely on telemedicine services must be able to credential the remote site providers within their own medical staff structure (Medicare Conditions of Participation.)
- Sources for creating a telemedicine credentialing system include appropriate language in:
  - Facility medical staff bylaws
  - Application for appointment and privileging
  - Standards of eligibility defined by applicable law/regulations
  - Delineation of privileges based on scope of practice and medical specialty
- Credentialing Procedures: Individual or by proxy (delegated credentialing)
- Should be included in telemedicine contracts

Quality/Peer Review

- Originating facilities are required to monitor distant-site telemedicine practitioners as with any other member of the medical staff.
- Look at applicable law to determine special rules related to reporting, confidentiality and qualified immunities associated with the peer review process
- Quality and peer review process should be addressed in the telemedicine services contract; make sure contract and bylaws are clear and consistent.

Telehealth Compliance Checklist - Hospitals

- Is there a compliant surrogate credentialing agreement in place
- Does the hospital relying on surrogate credentialing have the proper authority under its bylaws?
- Does the hospital engage in periodic re-credentialing assessments?
- Does the hospital conduct routine quality/peer review and report to the Distant Site Provider?
- Do the peer review and reporting processes comply with applicable law?

Telehealth Compliance Checklist - Providers

- Are the telehealth providers licensed in the state where the patient is located?
- Are there defined practice standards for patient examinations and remote prescribing?
- Are the providers documenting and maintaining patient records of encounters?
- Is there insurance coverage of telehealth services?
- Is the insurance carrier licensed in each state where the services are provided?
- Do the consent and authorization forms cover telehealth services?

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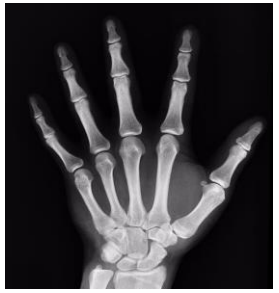
Theories of Liability

- Informed consent
  - Many US states explicitly require for telemedicine
  - Provider or patient-focused?
    - Standard of care
    - Causation
- Misdiagnosis
  - Teleradiology, e.g.
- Handoff errors
- Corporate negligence or enterprise liability



Theories of Liability, 2

- Communication disruption
  - Avoid telemedicine in emergencies
- Products claims
  - Instrument manufacturers,
  - conduit providers, software companies
- Liability for failure to use telemedicine
  - Telestroke, e.g.

Defendants' Challenges

- Rapport
  - Language
    - Radiologist has a duty to communicate findings based on the facts and circumstances of the case; failing to do so creates liability for a resulting injury. *Fowerbraugh v. Univ. Hosp*., 692 N.E.2d 1091, 1096 (Ohio Ct. App. 1997)
- Guidelines
  - Medical Board of Australia guidance on technology-based consultations, e.g.
- Injury through ignorance of technology
  - Leaning curve for robotic surgery, e.g.
- Ghosting: foreign radiologist interprets image; issues report officially signed by non-reading radiologist

Plaintiffs' Challenges

- Personal jurisdiction
  - **Civil** law: sue D in its domicile or in any jurisdiction where it commits a tort
    - Some: where P sustains injury
    - Others: where D committed tortious act
    - France: its courts may hear any case involving a French citizen
  - **Common** law: multi-factor approach
    - US: Plaintiff must show that:
      - (1) P's state has a long-arm statute
      - (2) D has minimum contacts with P's state: foreseeability of liability; "purposeful availment" of state's privileges and protections AND
      - (3) Exercise of personal jurisdiction is reasonable and does not violate "traditional notions of fair play and substantial justice" under Due Process Clause of Fourteenth Amendment
        - Indian model?
    - UK: asserts personal jurisdiction over foreign D if tort committed w/in its territory

Plaintiffs' Challenges, 2

- Personal jurisdiction, cont'd
  - Commercial or civil agreements that country is party to
    - Brussels Convention (EU only), e.g.
      - Member state may not employ "exorbitant' jurisdictional devices" against defendants domiciled in fellow member states
        - UK may not exercise jurisdiction by serving process to a D member-domiciliary while physically present in its territory
          - *Colt Indus. v. Sarlie*, 1 W.L.R. 440 (C.A. 1966) (service on an American defendant staying at a London hotel)
      - Mandates enforcement of judgments rendered by fellow member state courts

Plaintiffs' Challenges, 3

- Service of process
  - Registered agent in US or
  - Letters (legal) rogatory (comity)
    - Hague Service Convention (1965): unnecessary
      - India, e.g., not a signatory
    - InterAmerican Convention on Letters Rogatory and Additional Protocol: pre-printed forms to Central Authority
- Suing abroad:
  - Unfamiliar, less mature legal, regulatory, and financial systems
  - Fewer resources for recovery
    - Cannot compel foreign providers to be insured

Plaintiffs' Challenges, 4

- Choice of Law. Possibilities:
  - *Lex delecti* (Law of place of injury. UK and Australia, e.g.)
  - Restatement of Law: contract controls
  - "Center of gravity": domicile, residence, nationality, etc.
    - US states
  - Interest analysis: identify the jurisdiction with greatest interest
  - Policy: Don't apply foreign law that contravenes public policy
  - Lex fori (Law of jurisdiction where action is brought)
  - Rx: forum selection clauses

Plaintiffs' Challenges, 5

- Cross-cultural discovery
- Independent contractors
- Guidelines: hearsay
- Recovery:
  - Courts may uphold or disregard foreign judgments
    - US: transnational *res judicata* policy
  - A D who refuses to appear may void his policy
  - India, e.g.: severe case backlog
- **Arbitration**: International law gives arbitral awards more uniform and definite treatment
  - Legislation enables courts to enforce arbitration awards
  - Member countries of Friendship Commerce and Navigation ("FCN") treaties will enforce arbitration awards of fellow member countries

Insurance Coverage Issues

- Issues:
  - Assessing providers' existing coverage
  - Identifying compensable events
  - Selecting limits to match exposure in various countries
  - Rapidity of collection of adjudicated compensation

Agenda

- Telehealth Models
- Fraud & Abuse / Foreign Corrupt Practices Act ("FCPA")
- Privacy and Security
- Medical Licensure, Credentialing, and Privileging
- Professional / Product Liability
- Contracting Considerations & Dispute Resolution
- Questions

Contracting Considerations & Dispute Resolution

- Governing language
- Currency for payment
- Termination
- Dispute resolution
  - Process
  - Venue
  - Arbitration
    - American Arbitration Association
    - JAMS
    - International Chamber of Commerce (ICC) International Court of Arbitration
- Sovereign immunity
- Enforceability of “common” provisions

Contracting Considerations & Dispute Resolution

- Will payments be made in dollars or foreign currency?
  - If foreign currency, then the US-based entity assumes the risk/reward of fluctuations in the exchange rate
  - The foreign jurisdiction may have laws and regulations regarding currency exchange
  - Where will payment be received?
- Will the contracting entities be subject to tax in the foreign jurisdiction?
  - This may depend on the foreign jurisdiction's laws and tax treaties with the United States
- Will the foreign jurisdiction recognize and enforce contractual provisions regarding choice of law and choice of forum?

Contracting Considerations & Dispute Resolution

Jurisdiction	Foreign Exchange	Foreign Tax	Choice of Law/Forum
European Union	Contractual parties are free to use other official foreign currencies with legal tender status in the state of issuance.	Tax liability varies by EU member state, and the European Union's website summarizes the corporate tax laws of many member states.	Parties are free to choose the law applicable to the contract. Clauses specifying a court in an EU member state are generally enforceable per EU regulation, but the enforceability of forum selection clauses specifying non-EU member state courts may vary by member state.
China	The People's Bank of China (PBOC) and State Administration of Foreign Exchange (SAFE) regulate the flow of foreign exchange in and out of China.	Business vehicles providing services in China may be subject to Value Added Tax (VAT).	These provisions are generally respected if one of the contracting parties is not from China or the transaction otherwise qualifies as a foreign-related transaction.
India	The Foreign Exchange Management Act (FEMA) governs foreign exchange related transactions and allows the Reserve Bank of India and other financial institutions it authorizes to deal in foreign currencies.	If income accrues or arises in India, the foreign entity may be taxed.	Contracts entered into by an Indian party may not exclude Indian law. Indian courts generally enforce foreign arbitral awards but rarely enforce court orders from other jurisdictions.

Thank You

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