EXTENDING YOUR REACH WITH GLOBAL / INTERNATIONAL TELEHEALTH

Legal and Regulatory Matters

2019 Convergence Telehealth Summit
Mid-Atlantic Telehealth Resource Center

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# THE BASIC LEGAL AND REGULATORY DYNAMIC

<table>
<thead>
<tr>
<th>Same Same</th>
<th>But Different</th>
<th>Plus</th>
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<tbody>
<tr>
<td>• Practice of Medicine</td>
<td>• Practice of Medicine</td>
<td>• Regulation of Cross-Border Activity</td>
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<tr>
<td>• Legal and Regulatory Infrastructure</td>
<td>• Legal and Regulatory Infrastructure</td>
<td>• Application of Existing Requirements in Cross-Border Context</td>
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<tr>
<td>China</td>
<td>Germany</td>
<td>Abu Dhabi</td>
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<tr>
<td>Institution-based licensure</td>
<td>EU – national law applies</td>
<td>Subject to Federal-level regulations</td>
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<td>Two models: (1) institution-to-institution and (2) institution-to-patient</td>
<td>2018 and beyond</td>
<td>o Sometimes unclear division of power/authority</td>
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<tr>
<td>Foreign institution-to-patient telemedicine impermissible</td>
<td>Teleconsultation ban lifted</td>
<td>Physician-to-patient</td>
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<td>Direct-to-consumer telemedicine services impermissible</td>
<td>Permits physician-to-patient &amp; physician-to-physician</td>
<td>o Remote prescribing impermissible</td>
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<tr>
<td>Informed consent required</td>
<td>Must be “medically justifiable”</td>
<td>o No “invasive clinical interventions”</td>
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<tr>
<td></td>
<td>Informed consent required</td>
<td>o Facility licensure required</td>
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<tr>
<td></td>
<td>Reimbursement policy TBD (prior to 2018, €200/quarter)</td>
<td>Physician-to-physician</td>
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<td>o International distant providers permissible</td>
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**PLUS**

**FCPA**
- Anti-bribery law (government agents)
- Criminal and civil liability
- Health care industry is risky
  - Frequently government run
  - Mission is not a shield
  - Liability for actions of 3rd parties is possible
- DOJ reshuffling to form a combined health care fraud / FCPA unit
  - Enforcement in life sciences, but also investigations in health care

**Material Support**
- Prohibits supporting (A) terrorist acts or (B) terrorist organizations
- Criminal and civil liability
- Provision of medicine is exempt, but not the provision of services
- Broad definitions
  - Knowing
  - Personnel

**Practical Tips**
- Due diligence
  - Partner
  - Regulatory environment
- Have a compliance program
  - Oversight
  - Training
  - Discipline
- Have an exit strategy
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