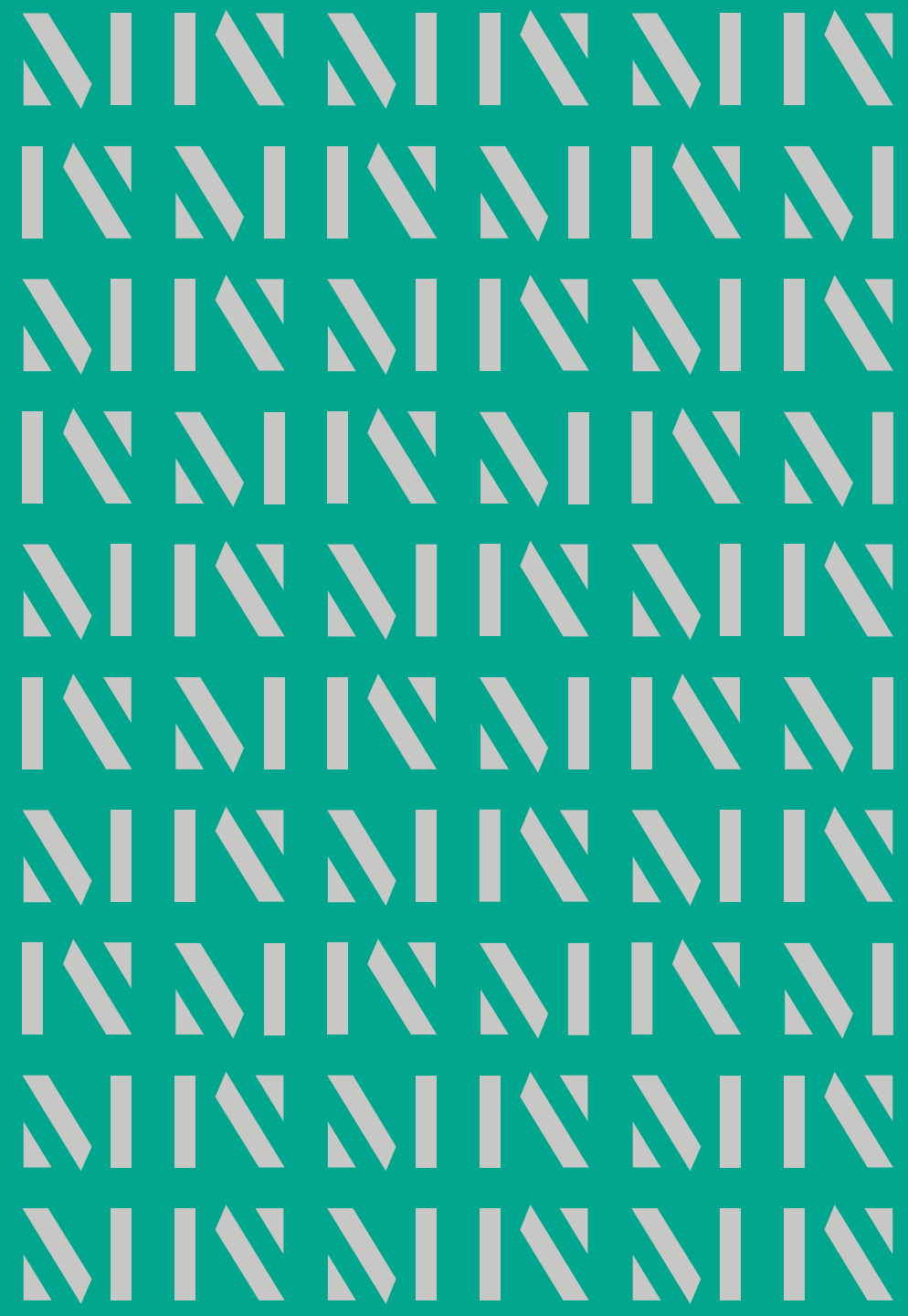


# EXTENDING YOUR REACH WITH GLOBAL / INTERNATIONAL TELEHEALTH

**Legal and Regulatory Matters**

**2019 Convergence Telehealth Summit  
Mid-Atlantic Telehealth Resource Center**

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# THE BASIC LEGAL AND REGULATORY DYNAMIC

## Same Same

- Practice of Medicine
- Legal and Regulatory Infrastructure

## But Different

- Practice of Medicine
- Legal and Regulatory Infrastructure

## Plus

- Regulation of Cross-Border Activity
- Application of Existing Requirements in Cross-Border Context

# SAME SAME, BUT DIFFERENT

## China

- Institution-based licensure
- Two models: (1) institution-to-institution and (2) institution-to-patient
- Foreign institution-to-patient telemedicine impermissible
- Direct-to-consumer telemedicine services impermissible
- Informed consent required

## Germany

- EU – national law applies
- 2018 and beyond
  - Teleconsultation ban lifted
  - Permits physician-to-patient & physician-to-physician
  - Must be “medically justifiable”
  - Informed consent required
  - Reimbursement policy TBD (prior to 2018, €200/quarter)

## Abu Dhabi

- Subject to Federal-level regulations
  - Sometimes unclear division of power/authority
- Physician-to-patient
  - Remote prescribing impermissible
  - No “invasive clinical interventions”
  - Facility licensure required
- Physician-to-physician
  - International distant providers permissible

# 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 3<sup>rd</sup> 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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