2015 Annual Meeting
May 3, 2015
Los Angeles, California

Legal Issues in Telemedicine
Business Models

Half Day Course
Meeting Room 403A
8:00 AM – 11:00 AM
Legal Issues in Telemedicine Business Models
Half Day Course
May 3, 2015 –12:00pm – 3:00pm
Room 403A

This practical, provider-oriented course offers valuable insights into different business models and associated key legal and regulatory issues facing telemedicine providers. Attendees will have the opportunity to engage in robust, open discussion of case studies and scenarios to promote understanding of telemedicine regulations as they pertain to each business model. Topics of interest include scope of practice and remote prescriptions; business models and operational issues; telemedicine reimbursement; fee splitting rules, anti-kickback statutes, and physician self-referral laws; and international telemedicine arrangements.

LEARNING OBJECTIVES
- Develop insight and understanding into the key legal and regulatory issues facing telemedicine providers in different business models/environments
- Obtain the resources and knowledge to take the steps necessary to implement or grow your telemedicine services
- Learn how to apply the rules to your own telemedicine business models and contractual arrangements
- Engage in robust, open discussion of case studies and scenarios to understand telemedicine regulations

Agenda

1. Intro and Handout Scenarios
2. Nathaniel Lacktman, JD, CCEP
   a. Business Models/Common Arrangements
   b. Compensation Methodologies
   c. Legal Issues regarding Telemedicine Business Models
   d. International Arrangements
3. Sarah Sosson, MPH, FACHE
   a. Service agreements with rural hospitals
   b. Credentialing
   c. Reimbursement & Payment Issues
   d. Assessing new service opportunities and partnerships
4. Break
5. Deborah Mulligan, MD, FAAP, FACEP
   a. Payor contracting arrangements and approaches
   b. Institutional contracting arrangements and approaches
   c. Employer arrangements and approaches
   d. Operational Issues
6. Michael Carter, BS
   a. Privacy & Security
   b. How consumerism affects system design
   c. Selecting and implementing technologies
   d. Encryption, integration, responsiveness
7. Scenario Handout Discussion
8. Q&A
Legal Issues in Telemedicine Business Models

Course Faculty

Nathaniel Lacktman, JD, CCEP, Partner, Foley and Lardner LLP (Moderator & Presenter): Nathaniel Lacktman is a partner with Foley & Lardner – named “Law Firm of the Year – Health Care Law” for the third consecutive year (2011-2014) by U.S. News and World Report. One of his primary practice areas is telemedicine and telehealth. He advises healthcare providers nationwide on the emerging opportunities and regulatory issues presented by telemedicine, including licensure, reimbursement, contracting, compliance, operations and strategy. He is a frequent speaker and author on telemedicine issues, and a member of the ATA. He received his law degree from the University of Southern California School of Law.

Michael Carter, BS, Enterprise Manager for Media and Telemedicine Systems, Partners HealthCare: Michael Carter is the Enterprise Manager for Media and Telemedicine Systems at Partners HealthCare in Boston, Massachusetts. With more than a decade of experience in Media technologies and Information Systems, Mr. Carter has been instrumental in launching strategic telemedicine programs and virtual care services that connect patients and clinicians. These programs have been in partnership with hospitals such as Brigham and Women's and Massachusetts General Hospital.

Deborah Mulligan, MD, FAAP, FACEP, Chief Medical Officer, MDLIVE: Dr. Deborah Mulligan received her Bachelor of Science degree from the University of San Francisco, her Medical Doctorate from the University of California, Los Angeles and completed pediatric emergency medicine training at Montefiore Medical Center/Albert Einstein College of Medicine. She is the Founder and Director of the Nova Southeastern University Institute for Child Health Policy. The Institute is a resource for health systems, policymakers, professional organizations, foundations and academic centers serving as a venue to nurture community-based advocacy and research as well as advising about disruptive
technologies and business models that accelerate transformation and constrain health expenditures. Board certified in pediatrics and pediatric emergency medicine, Dr. Mulligan is the Chief Medical Officer of MDLIVE, the nation’s leading provider of telehealth software and services. Prior leadership positions in health care, government and technology sectors include that of Pediatric Services Medical Director for nation’s 4th largest safety net hospital system and Co-President/CMO to Sitio Saludable, Inc. a national multi-disciplinary media startup company formed to provide broadcast and digital content to promote and support positive health behavior change among the U.S. Hispanic population.

Sarah Sossong, MPH, FACHE, Director of Telehealth, Massachusetts General Hospital: Ms. Sossong is the Co-Founder and Director of Massachusetts General Hospitals’s telehealth program, leading the design and implementation of new strategies utilizing telehealth technology platforms to support the organization’s transformation of health care across multiple specialties. Prior to Mass General, she managed strategic technology projects at Kaiser Permanente, including design and implementation of teledermatology services, and as a Lieutenant in the United States Navy, where she led and connected the business operations of 14 clinics through the implementation of the medical center’s first videoconferencing systems. She is a graduate of Princeton University and the University of California at Berkeley.
Legal Issues in Telemedicine Business Models

Nathaniel Lacktman, Esq., Partner, Foley and Lardner LLP

Michael Carter, BS, Enterprise Manager for Media and Telemedicine Systems, Partners HealthCare

Sarah Sosson, MPH, FACHE, Director of Telehealth, Massachusetts General Hospital

Deborah Mulligan, MD, FAAP, FACEP, Chief Medical Officer, MDLIVE
Telemedicine Panelists
Sample Business Models

1. Direct-to-consumer/patient
2. Institution-to-institution
3. Clinician-to-clinician
4. Internal oversight and processes
5. Chronic care management
6. Online patient access/portals/tech
7. mHealth, medical apps
8. Hardware/software
9. International
Sample Provider Arrangements

#1 Direct-to-Consumer/Patient
• DTC urgent care access
  – Patient contracts with provider for on-demand telemedicine services

#2 Institution-to-Institution
• Telestroke PSA with critical access hospital
  – Rural hospital contracts with academic medical center for on-demand telestroke services with 24/7 availability.

#3 Clinician-to-Clinician
• Peer-to-peer specialty consulting services
  – PCP group contracts with telepsychiatry specialist to consult on difficult cases.
Sample Provider Arrangements

#4 Internal oversight and processes
• eICU
  – Hospital creates internal eICU to have monitoring, responsiveness and oversight over inpatients

#5 Chronic Care Management
• RPM and follow-up for existing patients
  – CCM provider contracts with physician group for chronic care management and RPM services

#6 Online patient access/portals/tech
• Online second opinions and HIT portals
  – Dermatological oncology specialist offers online-based second opinion services to patients and their PCPs across the country, resulting in medical tourism opportunities.
Sample Provider Arrangements

#7 mHealth, medical apps
• Self-tracking apps, diagnostics, care support
  – mHealth-based smoking cessation and medication adherence software with RT-transmittal of data analysis and patient utilization to provider group

#8 Hardware/software
• On-site kiosks (schools, factories, oil rigs)
  – Professional telemedicine-based services in remote areas using kiosks or other telediagnostic equipment modules

#9 International
• U.S. to China telemedicine
  – U.S.-based hospital contracts with China-based medical center to provide telemedicine-based consults, fellowship educational opportunities, research collaboration and other services.
Sources of Compensation

- Government (Medicare, Medicaid)
- Commercial Plans (incl. Medicare Advantage, Medicaid Managed Care)
- Employer-pay (incl. self-funded plans)
- Org-to-org, peer-to-peer
- Patient self-pay
- Cost savings
Compensation Methodologies

- FFS
- Capitated
- Hybrid models
- Shared savings, risk-based
Compensation Methodologies

**Fee for Service**

- **PAYOR**
- **RISK**
- **$ (FFS)**

- **PROVIDER**

**Capitated**

- **PAYOR**
- **$ (PMPM)**

- **PROVIDER**
- **RISK**
Compensation Methodologies

RURAL HOSPITAL

- Monthly Fee
- Add-on FFS

PROVIDER

- Flexibility
- Scalability
- Shared risk
Legal & Regulatory

• Fraud & Abuse Concerns
  – Anti-kickback Statute
  – Physician Self-Referral
  – Civil Monetary Penalty Law
  – State Laws
    • Fee-Splitting
    • Patient Brokering
    • Insurance Laws
    • Corporate Practice of Medicine
Telemedicine Arrangements

Non-physician Owners

MSO

Physician Owners

PC

Contracted/Employed Physicians

Management Services

$\$
International Arrangements

• Examples:
  – Peer to peer
  – Education/consulting
  – Cross-training fellows
  – Online opinions
  – Medical tourism
  – Direct care
International Arrangements

- Regulatory considerations
  - Practice of medicine
  - Licensure
  - Privacy
  - Data protection; data ownership
  - Risk and enforcement profile
  - Quickly-changing legal landscape (countries with developed telemedicine vs. emerging countries)
International Arrangements

- Establishing business operations
- Tax considerations
- Dispute resolution
- Jurisdiction and choice of law
- Intellectual property

- International Example: China
Telemedicine is Not Scary!
Nathaniel Lacktman
Foley & Lardner LLP
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nlacktman@foley.com
Foley.com/telemedicine
You are a health system that currently uses several different E.H.R. software programs. The system wants its patients and doctors to use virtual care services and access to medical records from mobile devices.

**QUESTION:**

1. Name three challenges you will face in this endeavor.
2. How would you approach solving one of these challenges?
Your company wants to offer direct-to-patient virtual dermatology physician services across the country. Your company is not owned by doctors.

QUESTION:

1. What corporate structure would you use and why?
2. How would you deal with malpractice, misdiagnosis and patient follow-up?
You are a rural Critical Access Hospital in need of specialty physician services, but do not have the patient volume to support a full-time specialist on staff. The CEO wants you to explore a telemedicine arrangement with a major hospital.

**QUESTION:**

1. What are three considerations to keep in mind when exploring this project?
2. How would you structure the payment under a contract like this?
You are a primary care physician group and want to offer telemedicine consults to your existing patients in the evenings (when your brick and mortar location is closed).

QUESTION:

1. What are the main clinical-operational issues to address?
2. How would you approach billing or payment for these services?
You are a hospital that is contracting with a telemedicine equipment manufacturer. The manufacturer has offered to give you a dozen iPads for the physicians to use in connection with the telemedicine equipment.

QUESTION:

1. Can the hospital give the iPads to the doctors?
2. If so, are there any restrictions or limitations?
Legal Issues in Telemedicine

*Perspectives on Reimbursement, Compensation, and Evaluating New Business Opportunities*

Sunday, May 3rd from 8AM-11AM in Los Angeles, CA

American Telemedicine Association 20th Annual Conference
Massachusetts General Hospital
Massachusetts General Hospital

Original Campus

3rd Oldest General Hospital in the US • Founded in 1811 • Flagship teaching hospital for Harvard Medical School
MGH Main Campus and Subsidiaries
1.5 million outpatient/ED visits • 1,541 beds • 47k inpatient admissions
Telehealth – a 50 year journey
MGH Focus Areas

Internal
Population Health Management

External
Episodic Care Management
Telehealth Activity at MGH

Real Time “Synchronous”

Virtual Visit
- Video visit between MGH MD and patient

Virtual Consult
- Video consult from MGH MD to patient’s MD

Store and Forward “Asynchronous”

eVisit
- Online exchange of medical info between MGH MD & patient

eConsult
- Online consult from MGH MD to patient’s local MD

1 Exchange where the provider gives the patient medical advice
2 Exchange where the MGH consultant “Expert” gives MGH provider or external community provider medical advice
Telehealth Reimbursement and Business Case

- Licensure
- Credentialing
- Scope of Practice
- Type
- Privacy & Security
- Reimbursement
- Technology
- Professionals
- International Arrangements
An uncertain landscape...
An uncertain landscape...
Financial Alignment

Business Case

Payer Reimbursement

Incentives
Financial Alignment: Business Case

- Regional market share
- Population health
- New revenue source
- Value/cost savings
- Patient-centered care
- Access to referrals
- Resource management
- Accountable Care
Financial Alignment: Payer Reimbursement

External Reimbursement
- Private Payer/Commercial Insurance, e.g., BCBS
- Public Payer, e.g., Medicaid, Medicare
- Employer-Pay
- Self-Pay
- Contracts with Community Hospitals, Employers, Insurers

Internal Reimbursement
- Hospital Funded
Medicare telehealth coverage

- Reimburses for telemedicine services when the originating site (patient location) is in a HPSA or a county outside a Metropolitan Statistical Area (MSA).
- Originating site must be a medical facility and not the patient's home (e.g., practitioners' offices, hospital, and rural health clinics).
- Only covers face-to-face, interactive video consultation services where the patient is present. (S&F in AK and HI)
- Limited set of covered services.
Medicaid telehealth coverage

- Approximately 47 states offer some form of Medicaid reimbursement for telehealth services
- Generally live video
- Minority of states cover store & forward or remote monitoring
Commercial insurance telehealth coverage

- Key element driving adoption and expansion
- As of April 7, 2015, 24 states plus DC require it
- Some payors beginning to voluntarily offer it to enrollees
<table>
<thead>
<tr>
<th>State</th>
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<tbody>
<tr>
<td>Arizona</td>
<td>Hawaii</td>
<td>Mississippi</td>
<td>Oklahoma</td>
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<td>Arkansas</td>
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<td>California</td>
<td>Louisiana</td>
<td>Montana</td>
<td>Tennessee</td>
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<td>Colorado</td>
<td>Maine</td>
<td>New Hampshire</td>
<td>Texas</td>
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<tr>
<td>DC</td>
<td>Maryland</td>
<td>New Mexico</td>
<td>Vermont</td>
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<td>Georgia</td>
<td>Michigan</td>
<td>New York</td>
<td>Virginia</td>
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# Reimbursement Resources

## Telemedicine in California

<table>
<thead>
<tr>
<th>Parity:</th>
<th></th>
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<tbody>
<tr>
<td>Private Insurance</td>
<td>A</td>
</tr>
<tr>
<td>Medicaid</td>
<td>B</td>
</tr>
<tr>
<td>State Employee Health Plan</td>
<td>A</td>
</tr>
</tbody>
</table>

### Medicaid Coverage & Conditions of Payment:

- Patient Setting: A
- Eligible Technologies: C
- Distance or Geography Restrictions: A
- Eligible Providers: C
- Physician-provided Services: B
- Mental/Behavioral Health Services: B
- Rehabilitation: F
- Home Health: F
- Informed Consent: C
- Telepresenter: B

### Innovative Payment or Service Delivery Models:

- State-wide Network: ✔
- Medicaid Managed Care: ✔
- Medicare-Medicaid Dual Eligibles: ✔
- Health Home: ✔
- HCBS Waiver: ✔
- Corrections: ✔
- Other: ✔

**Innovation:** California Telehealth Network supports broadband connections of many institutions state-wide.

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## Telemedicine in Massachusetts

<table>
<thead>
<tr>
<th>Parity:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Private Insurance</td>
<td>F</td>
</tr>
<tr>
<td>Medicaid</td>
<td>B</td>
</tr>
<tr>
<td>State Employee Health Plan</td>
<td>F</td>
</tr>
</tbody>
</table>

### Medicaid Service Coverage & Conditions of Payment:

- Patient Setting: A
- Eligible Technologies: C
- Distance or Geography Restrictions: A
- Eligible Providers: A
- Physician-provided Services: A
- Mental/Behavioral Health Services: B
- Rehabilitation: F
- Home Health: F
- Informed Consent: A
- Telepresenter: A

### Innovative Payment or Service Delivery Models:

- State-wide Network: ✔
- Medicaid Managed Care: ✔
- Medicare-Medicaid Dual Eligibles: ✔
- Health Home: ✔
- HCBS Waiver: ✔
- Corrections: ✔
- Other: ✔

**Innovation:**
- MA is bordered by NH and VT which have private insurance parity laws. No telemedicine parity law despite a multi-year effort to introduce legislation regarding coverage under private insurance, Medicaid and state employee plans.
- Medicaid offers coverage under select managed care plans but not under FFIs.
- Authorized to cover remote monitoring for home health agencies. Rules are in development.
- Received grant to establish a National Sexual Assault TeleNursing Center that will use telemedicine technology to provide 24/7, 365 day remote expert consultation by 24-25 MA Sexual Assault Nurse Examiners (SANEs) to clinicians caring for adult and adolescent sexual assault patients in remote and/or underserved regions of the United States.
- Partners Telestroke Network – members receive 24-hour acute neurology/stroke expertise-on-demand.

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**Credit:** ATA’s State Telemedicine Policy Center (4/7/15)
Financial Alignment: Payer Reimbursement

- Employer-pay arrangements
- Self-pay arrangements
- Contracts with Community Hospitals, Employers, Insurers

Service Agreement and Notice of Non-Coverage

Department of Psychiatry Virtual Visit Pilot

<table>
<thead>
<tr>
<th>Patient’s Name</th>
<th>Patient’s MRN</th>
<th>Patient’s DOB</th>
</tr>
</thead>
</table>

1. Notice of Non-Coverage

Your health insurance plan has established rules for the reimbursement of health care services. Virtual Visits do not currently meet these coverage requirements. Therefore:

- During the TelePsychiatry Virtual Visit Pilot, visits now through December 31, 2013 will be free of charge. Policies for any TelePsychiatry Virtual Visits after December 31, 2013 are subject to change.

Patient Agreement:

I have been notified by my physician or designee that my insurance or worker’s compensation plan will not provide payment for the services identified above. I understand that I have the right to decide whether to receive these services. I am also aware that teleconference technology in use is secure, reliable and robust, but may experience incidental connectivity issues. I have decided to receive these services, and agree to be personally and fully responsible for necessary electronic equipment for the TelePsychiatry Virtual Visit Pilot.

By signing below, I acknowledge that I have read and agree to being bound by the above Patient Agreement.
# Financial Alignment: Reimbursement

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<th>Location of Services</th>
<th>Clinical “Tele” Specialty</th>
<th>Funding Source</th>
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<td>Payers</td>
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<td>Acute-ED</td>
<td>Burns, Neurology, Neurosurgery (Brain Tumor), Pediatrics, Stroke</td>
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<tr>
<td>In-Patient</td>
<td>Burns (Wound Care), Critical Care, Neurology, Pediatrics (PICU/NICU), Plastic Surgery, Urology</td>
<td>X</td>
</tr>
<tr>
<td>Outpatient Clinic</td>
<td>Burns (Wound Care), Cardiology, Dermatology, Pain Management, Neurology, Pediatric Subspecialties</td>
<td></td>
</tr>
<tr>
<td>Patient Home</td>
<td>Cancer Center, Cardiology, Neurology, Pediatrics, Primary Care, Psychiatry</td>
<td></td>
</tr>
<tr>
<td>Second Opinions</td>
<td>Multiple Specialties</td>
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## Financial Alignment: Reimbursement

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Financial Alignment: Incentives

- Patients
- Departments
- Health Systems
- Physicians

Incentives
Financial Alignment: Incentives for MGH Providers

Telehealth “Virtual CPT” Codes with wRVUs and $$$

- Type of Activity
- New vs. Established Patients
- Time Based

<table>
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<th>Virtual Visit</th>
<th>Virtual Consult</th>
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<td>VIR-EST-VID</td>
<td>VIR-NEW-MMP</td>
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<tr>
<td>eVisit</td>
<td>eConsult</td>
</tr>
<tr>
<td>VIR-EST-ONL</td>
<td>VIR-NEW-MD</td>
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Financial Alignment: Incentives for Providers

Reimbursement Level and Approach

Show me the money!
Financial Alignment: Incentives for Departments

Departmental Overhead and Support
Telehealth Privacy/Security

- Patient Consent
- Patient Registration
- Visit / Consult Documentation
TeleHealth Patient Consent Form

Introduction:
I understand that my health care could be improved by talking with my MGH Clinician using electronics (TeleHealth). I understand that my Clinician will tell me about the benefits and risks of TeleHealth. After this talk, I will decide if I want to take part in TeleHealth. If I do want to take part in TeleHealth, I need to sign this form and bring it back to my Clinician. I understand that a signed copy of this form will be placed in my health record.

I understand that I do not have to take part in TeleHealth, and that I may stop at any time.

I, (print name) ______________________, agree to use TeleHealth as specified by my Clinician.

Signature (Patient/healthcare agent/guardian/family member) __________________________ Date __________________________

A FOUNDING MEMBER OF PARIS.
Privacy/Security: Visit / Consult Documentation

TeleHealth Patient Visit

Patient name: __________________________

Patient MRN: __________________________

Patient age, DOB: __________________________

Patient gender: __________________________

Visit type: 
- [ ] Initial Visit
- [ ] Follow-up Visit

Date: __________________________

Communication interface: 
- [ ] Phone
- [ ] Video
- [ ] Other

Patient location/present during encounter: 
- [ ] Outpatient
- [ ] ED
- [ ] Inpatient
- [ ] Other

Family present and who: 
- [ ] Yes
- [ ] No

Total time of encounter: __________________________
MGH TeleHealth Credentialing Experience

1. Consults to community hospitals
2. TJC and Medicare credentialing recommendations – and the Board of Registration of Medicine in Massachusetts and Community Hospital Bylaws
MGH TeleHealth Credentialing Experience

1. Consults to community hospitals

2. TJC and Medicare credentialing recommendations – and the Board of Registration of Medicine in Massachusetts and Community Hospital Bylaws
Legal Issues in Telemedicine Business Models

Deborah Ann Mulligan, MD FAAP FACEP
MDLIVE, Inc. | Chief Medical Officer
Professor and Director Institute for Child Health Policy
Nova Southeastern University
dmulligan@mdlive.com | www.mdlive.com
What can a sustainable telemedicine business model look like?

- Establish a Vision
- Access to Care Model
- Cost Savings Model
- Access to Market Model

- Building a Long Term Financial Plan
  - Revenue model show clear revenue management.
  - Cost saving model show your benchmark and a method to clearly measure the savings.
  - Strategic model show a way to measure strategic contribution or result.
Horizontal vs. Vertical Implementation
The successful strategy is a balanced approach.
Integrated Connected Care

Telemedicine Verticals:
- Rural Site
- Senior Center
- Hospital
- Self-insured Employer
- Mobility
- Remote Site
- Residential
- Retail Clinic
- School
- Remote Clinic
- Retail Mall
- Physician Practice
- Walgreens
• Establish a governance structure
• Revenue model*
• Human resources
• Processes and policies
• Technology
• Specialized telehealth technologies
  • telemonitoring, remote diagnostics and remote robotics
• General digital solutions
• IT infrastructure needed to support telehealth and digital solutions

*Benefits beyond revenue
• Value of:
  • outreach, integration, perception
  • partnerships
• Outcome target of population health:
  • Measure: inpatient days per 1000
  • Patient engagement, self-care, knowledge, skills, attitudes, behaviors
• Business License
• Software License
  • Delivery of consultation (Video, Audio, etc.)
  • Medical Imaging in the Cloud
  • Health IT
    • Administrative Billing
    • Electronic prescribing (e-prescribing)
    • Computerized provider order entry
    • Clinical decision support systems
    • Electronic health records
    • E-mail communication with patients
    • Mobile medical carts
    • Handheld medical peripherals
  • Scheduling of Provider Network
• Professional License
  • Physician License
    • Credentialing
    • Verification

Licensure
We must ensure that our regulatory environment appropriately balances the exciting advances in technology for patients, while still maintaining safeguards that allow innovation. To put it in perspective, the legal structure around telehealth was established in 2000, when cell phones were still just phones.”

— Former US Senator Tom Daschle
Physicians

State Licensed, Board Certified, and credentialed physicians

Specialized training in communication and diagnosing patients over the phone and through online video

Professional Liability, Errors and Omissions, or Medical Malpractice Insurance

Consent Forms, Policy and Procedures

Accreditation of quality and efficiency of healthcare management

NCQA

URAC

ATA Accreditation for Online Patient Consultations
• Scope of Practice
• Remote Prescribing
• Informed Consent
• Recordkeeping
• Terms of Use and Liability
• Malpractice Insurance
Quality Standards, Policies, Evaluation Tools

- Applicable accrediting and regulatory agencies
- HIPAA Requirements
- Patient Protection and Affordable Care Act
- Physician Onboarding and Recruiting
  a. Education and Training of Providers
  b. National Guideline driven protocols
  c. Evaluation of Provider Consultation
• **24/7 Call Center**
  • 100% healthcare industry focus
  • Trained to express empathy and patience
  • Answer member health questions
  • Triage to MDLIVE doctors and therapists
  • Take personal health histories
TELEHEALTH IS BECOMING UNIVERSAL

- Full Services – Video + Phone
- Services Limited to Phone
- Services Temporarily Suspended
- Limited Prescription Services (See below)

Alaska
Hawaii

MDLIVE™
• Recordkeeping
  • Account Management and Reporting
- Demographics
  - Population health management
  - Readmission rates
- Activation of new telehealth patients
  - Utilization
    - Repeat Visits
- QA Matrix
  - Standard of Care
    - Prescription Rates
- Time Study
  - Call Center
  - Consultation Duration
- Patient Satisfaction
  - Access
  - Reported technology comfort and adoption
  - Trust and satisfaction with care provided
- Provider Satisfaction
• Terms of Use and Liability
  • Operate HIPAA and PHI-compliant systems that ensures private, secure and confidential connections
Proactively Approaching Telehealth Informed Consent

State Implementation of Telehealth-Specific Consent Laws

Mitigating the Risk of Consent-Based Claims
• Language introducing and explaining the telehealth process in a way that patients can easily understand;

• Description of the expected risks and benefits of telehealth services; and

• Other information necessary for the patient to have a complete understanding of the telehealth process (i.e., available alternatives,

https://www.mdlive.com/consumer/informed_consent.html
Deborah Ann Mulligan, MD FAAP FACEP
MDLIVE, Inc. | Chief Medical Officer
Professor and Director Institute for Child Health Policy
Nova Southeastern University
dmulligan@mdlive.com | www.mdlive.com
Legal Issues in Telemedicine Business Models

*Michael Carter, BS, Enterprise Manager for Media and Telemedicine Systems, Partners HealthCare*
Telemedicine Legal Considerations

- Licensure
- Credentialing
- Scope of Practice
- Operational
- Privacy & Security
- Reimbursement
- Technology
- International
- Business Models / Fraud & Abuse
Technology and HIT Systems

Business Challenges

- Business Process
- IT Systems
- Technology

Business Solutions
IT Components

- Computing Devices
- Data Management
- Operating Systems
- Enterprise Systems
- Integration
- Networking Telecomm
Mediating Factors

- Environmental
- Cultural
- Structure
- Business Processes
- Politics
- Decision Support
Privacy and Security Overview

The challenge: protect PHI as it moves through the healthcare system

- **Potential obstacles:**
  1. **Internal**
     - Workflow
     - Politics
     - Organizational Culture
  2. **External**
     - Hackers
     - Identify Theft
     - State Sponsored Attacks
     - Consumerization of IT
<table>
<thead>
<tr>
<th><strong>Business Challenge</strong></th>
<th><strong>Risk</strong></th>
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<td>Direct-to-patient/consumer</td>
<td>Network security</td>
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<td>Institution-to-institution</td>
<td>Secure access</td>
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<td>Clinician-to-clinician consulting</td>
<td>Work Flow</td>
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<tr>
<td>Internal oversight and processes</td>
<td>Scale</td>
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<tr>
<td>Chronic care management</td>
<td>Data Management</td>
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<td>Online patient access/portals/tech</td>
<td>Integration with Clinical Systems</td>
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<tr>
<td>mHealth, medical apps</td>
<td>Network Security</td>
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<tr>
<td>Hardware/software</td>
<td>Governance</td>
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</tbody>
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Technology Selection

- **Build vs Buy**
  1. Agility versus sustainability
  2. The Business Associative Agreement (BAA)
  3. The use of technology consultants
  4. How to choose the right technology partner?

- What is feasible?

- What does scale look like?

- Could this be an Enterprise System?
Integration

- How can technology integration add value?
  1. Automation
  2. Cost Reduction
  3. Capacity building

- Where to focus
  1. Reducing disparate systems
  2. Tying in with clinical systems
  3. SaaS and PaaS based models
Technology Implementation

- How to start out secure and end up at scale
- Phased approach versus “big bang”
- Don’t forget about support processes!
- Capital costs versus Operational costs
  - Contracting
  - Support Needs
  - Capacity
Approaches to Security

- Cyber Security Changing Landscape
- Encryption and HIPAA compliance
- Two Factor Authentication
- Data Management
Security Breaches

- 62% increase in security breaches since 2013
- 2.5 billion exposed records in 2014
- Telehealth is an unfamiliar territory to most security professionals

How to prevent IT security breaches

1. Third Party Code Audits
2. Hosting Security Reporting
3. Active Monitoring
4. Standards
Contact Information

Michael Carter, BS
Enterprise Manager of Media and Telemedicine Systems
Partners Healthcare
Information Systems, Partners Collaborative Media
617-726-5740
mcarter7@partners.org
Telehealth Compliance Checklist

Professionals

☐ Is the telehealth professional licensed in the state where the patient is located?
☐ Are there practice standards in that state for patient examinations and remote prescribing, and are they being followed?
☐ Are appropriate professionals documenting and maintaining patient records of the telehealth encounters?
☐ Do the liability policies of the patient site facility and telehealth provider cover telehealth services?
☐ Is the telehealth provider’s insurance carrier licensed in every state where services are provided (patient located)?

Medicare/Medicaid

☐ Do services qualify as covered telehealth services?
☐ Are services being coded to properly reflect the place of service?

Commercial Insurance, Medicare Advantage, and Medicaid Managed Care

☐ Are the telehealth provider’s services covered by commercial insurance? (does the state require coverage for telehealth service?)
☐ Do the provider’s contracts reflect this coverage and include negotiated payment amounts?
☐ Have reimbursement options other than FFS been evaluated, such as PMPM, capitation add-ons, or hybrid risk-bearing?

Consent

☐ Does the informed consent form account for services provided via telehealth?
☐ Does the consent recognize patient freedom of choice?

Fraud & Abuse

☐ If Medicare/Medicaid recipients are receiving care, does the arrangement comply with the federal Anti-Kickback Statute? (Check provider/vendor arrangements and patient incentive programs)
☐ If Medicare/Medicaid recipients, does the arrangement comply with the federal Civil Monetary Penalties Law? (Check provider/vendor arrangements and patient incentive programs)
☐ Does any physician financial arrangement comply with the Stark Law? (Check all physician benefits, including software and equipment tech, to ensure that a Stark exception is satisfied, if required)
☐ Does the arrangement comply with state patient brokering laws and anti-kickback statutes? (Check provider/vendor arrangements and patient incentive programs)
☐ Does the arrangement comply with state corporate practice of medicine rules? (Check both the “distant site”, and where the patients are located)
☐ If capitated or PMPM compensation, does the arrangement comply with state insurance laws? (Check if exempt and, if not, conduct risk assessment)

Credentialing

☐ Is there a credentialing by proxy agreement in place that meets all required elements?
☐ Is the hospital relying on proxy credentialing, and does it have proxy credentialing provisions in its bylaws?

Privacy & Security

☐ Are there privacy and security protocols for the telehealth offerings?
TELEMEDICINE CREDENTIALING AGREEMENT

THIS TELEMEDICINE CREDENTIALING AGREEMENT is entered into and effective as of the ___ day of _____________, 201__ (“Effective Date”), by and between _______________ (“Distant Site Hospital”), and _______________ (“Originating Site Hospital”).

WHEREAS, Distant Site Hospital is a Medicare-participating acute care hospital in the State of ________;

WHEREAS, Distant Site Hospital reviews and approves the credentials of Telemedicine Providers to provide clinical services to patients via electronic communication;

WHEREAS, Originating Site Hospital is a Medicare-participating hospital in the State of ________;

WHEREAS, Originating Site Hospital wishes to rely in part on the credentialing process utilized by the Distant Site Hospital to facilitate the credentialing of certain Telemedicine Providers at the Originating Site Hospital and thereby enable the Telemedicine Providers to provide Telemedicine Services to patients of the Originating Site Hospital; and

WHEREAS, the parties wish to establish a telemedicine credentialing and privileging process at the Originating Hospital that satisfies the requirements of the Centers for Medicare and Medicaid Services (“CMS”), The Joint Commission (“TJC”), and applicable state and federal laws;

NOW, THEREFORE, in consideration of the mutual covenants and agreements of the parties hereto, it is understood and agreed by the parties as follows:

I. Definitions

As used in this Telemedicine Credentialing Agreement, the following terms, when capitalized, shall have the following meanings:

A. “Credentialing” means the evaluation and verification of Telemedicine Providers’ qualifications and competence to provide specific Telemedicine Services.

B. “Credentialing Program” means the process by which Telemedicine Providers’ qualifications and competence are evaluated and verified.
C. “Originating Site” means the site where patients are physically located when receiving the Telemedicine Services for purposes of this Agreement, namely the Originating Site Hospital location.

D. “Telemedicine Privileges” means the approved clinical privileges obtained by a Telemedicine Provider at the Distant Site Hospital and/or Originating Site Hospital to provide Telemedicine Services to patients at said hospital(s).

E. “Telemedicine Provider” means a health care professional who is duly qualified, credentialed and privileged to perform specific Telemedicine Privileges, or is seeking Telemedicine Privileges, in accordance with the terms of this Agreement.

G. “Telemedicine Services” means the clinical services provided by Telemedicine Providers via telemedicine technologies.

II. Distant Site Hospital Responsibilities:

A. **Compliance with Conditions of Participation and TJC Standards.** Distant Site Hospital is a Medicare-participating hospital. Distant Site Hospital’s Credentialing Program has been reviewed and approved by its governing body, and satisfies all applicable Medicare Conditions of Participation related to Credentialing and the Telemedicine Services, including but not limited to the requirements at 42 C.F.R. § 482.12(a)(1) through (7) and 42 C.F.R. § 482.22(a)(1) through (a)(3), and all applicable requirements in the Medical Staff chapter of TJC’s Comprehensive Accreditation Manual for Hospitals, including, but not limited to, MS.06.01.01 through MS.06.01.13. The governing body of the Distant Site Hospital, through its Credentialing Program:

   A. Determines, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;
   B. Appoints members of the medical staff after considering the recommendations of the existing members of the medical staff;
   C. Assures that its medical staff has bylaws;
   D. Approves medical staff bylaws and other medical staff rules and regulations;
   E. Ensures that the medical staff is accountable to the governing body for the quality of care provided to patients;
   F. Ensures the criteria for selection are individual character, competence, training, experience, and judgment; and
   G. Ensures that under no circumstances is the approval of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.
B. Credentialing. The Distant Site Hospital shall evaluate and, if appropriate, approve applications for Telemedicine Privileges at the Distant Site Hospital.

A. The Distant Site Hospital shall establish and maintain a current list of Telemedicine Services approved for each Telemedicine Provider who obtains Telemedicine Privileges at the Distant Site Hospital, and shall provide to the Originating Site Hospital (in substantially the form of Exhibit A hereto) a current list of Telemedicine Services that have been approved at the Distant Site Hospital for each Telemedicine Provider who is seeking or has obtained Telemedicine Privileges at the Originating Site Hospital in accordance with this Agreement.

B. Upon reasonable request and subject to State law limitations, the Distant Site Hospital shall provide the Originating Site Hospital with a copy of its bylaws and medical staff rules and policies related to credentialing and peer review, as reasonable evidence of the Distant Site Hospital’s compliance with Section II(A), above.

C. Upon reasonable request and subject to State law limitations, the Distant Site Hospital shall provide the Originating Site Hospital with the complete credentialing and privileging file for each Telemedicine Provider who has been approved for Telemedicine Privileges at the Originating Site Hospital in accordance with this Agreement.

C. Recredentialing. The Distant Site Hospital shall conduct re-credentialing of the Telemedicine Providers in accordance with its established policies and procedures, applicable Medicare Conditions of Participation, and applicable TJC standards, and will include in its re-credentialing process patient complaints, adverse events, and other relevant information provided to the Distant Site Hospital by the Originating Site Hospital.

D. Changes in Privileges; Disciplinary Action. The Distant Site Hospital shall notify the Originating Site Hospital as soon as reasonably practicable of any change in privileges of a Telemedicine Provider who is providing Telemedicine Services to the Originating Site Hospital as a result of this Agreement, and shall notify the Originating Site Hospital of any action classified as disciplinary action under applicable Distant Site Hospital policies taken against a Telemedicine Provider.
III. Originating Site Hospital Responsibilities:

A. Credentialing by Proxy. The governing body and the medical staff of the Originating Site Hospital may choose to rely upon the Distant Site Hospital’s Credentialing Program decisions when making its own credentialing and privileging decisions regarding the Telemedicine Providers pursuant to this Agreement, provided that the governing body of the Originating Site Hospital ensures compliance with the requirements at 42 C.F.R. §482.22(a)(3). The Originating Site Hospital shall ensure that each such Telemedicine Provider holds a license issued or recognized by the State where the Originating Site Hospital is located. The Originating Site Hospital shall also ensure that the privileges it grants each Telemedicine Provider at the Originating Site Hospital in accordance with this paragraph do not exceed the privileges granted to that Telemedicine Provider at the Distant Site Hospital.

B. Originating Site Performance Information. The Originating Site Hospital shall maintain evidence of its internal reviews of each Telemedicine Provider’s performance and quality at the Originating Site Hospital and shall provide such performance and quality information to the Distant Site Hospital for the Distant Site Hospital’s periodic appraisals of the Telemedicine Providers who are subject to this Agreement. At a minimum, this performance and quality information shall include all adverse events that result from the Telemedicine Services provided by each Telemedicine Provider to the Originating Site Hospital’s patients and all complaints the Originating Site Hospital has received about each Telemedicine Provider (including but not limited to adverse outcomes related to sentinel events that are considered reviewable by TJC). The Originating Site Hospital shall notify the Distant Site Hospital as soon as reasonably practicable of any action taken against a Telemedicine Provider by the Originating Site Hospital which is classified as disciplinary under the Originating Site Hospital’s credentialing policies.

C. State and/or Federal Disciplinary Action. The Originating Site Hospital shall notify the Distant Site Hospital as soon as reasonably practicable of any action taken by a state or federal authority which restricts or limits the practice or professional prerogatives of a Telemedicine Provider in the Originating Site Hospital’s State, including an involuntary suspension, termination, reduction or involuntary change in licensure status.

IV. Peer Review Activities. The activities required to be conducted pursuant to this Agreement are structured to operate as professional review activities under the Health Care Quality Improvement Act 42 U.S.C. §§ 1101, et seq., and as protected peer review activities pursuant to applicable state statutes. The parties, including their employees and agents, shall to the extent possible, conduct themselves at all times in a manner that
maximizes the federal and state law confidentiality and related protections and privileges that may be available for the peer review processes, proceedings, records and reports described herein, so as to maintain the confidentiality of such processes, proceedings, records and reports, and protect such processes, proceedings, records and reports from discovery or introduction into evidence in any administrative, judicial or quasi-administrative or judicial tribunal or proceeding.

V. Notices. All notices, requests and other correspondence related to telemedicine Credentialing, medical staff membership or privileges between the parties related to this Telemedicine Credentialing Agreement shall be addressed to the credentialing offices of the Originating Site Hospital and the Distant Site Hospital.

VI. Term and Termination. This Telemedicine Credentialing Agreement shall commence on the Effective Date and shall continue unless terminated as provided for herein.

A. Without Cause. Either party may terminate this Telemedicine Credentialing Agreement at any time, without cause on thirty (30) days’ prior written notice to the other party, which notice shall specify the effective date of termination.

B. For Cause. Either party may terminate this Telemedicine Credentialing Agreement upon the breach of any material term of the Agreement by the other party, which breach has not been cured to the satisfaction of the non-breaching party within fifteen (15) days after written notice of such breach.

C. Mutual Consent. The parties may terminate this Telemedicine Credentialing Agreement at any time by mutual written consent.

VII. Miscellaneous.

A. Amendment. No alteration or modification of this Agreement shall be valid unless made in writing and executed by each of the parties hereto.

B. Counterparts. This Agreement may be executed in more than one counterpart, and each executed counterpart shall be considered as the original.

C. Successors. This Agreement shall be binding upon and shall inure to the benefit of the parties and their respective successors and representatives.

D. Notices. Any notice or other communication by one party to the other shall be in writing and shall be given, and be deemed to have been given (i) if hand delivered, upon delivery, (ii) if mailed, postage prepaid, certified mail (return receipt requested),
on the second business day after mailing, or (iii) if sent by an overnight courier service, the next business day after depositing with such courier, in each case addressed as follows:

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<th>Originating Site Hospital:</th>
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<th>Distant Site Hospital:</th>
<th>Hospital</th>
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Either party may change the address for notice by notifying the other party, in writing, of the new address.

E. **Assignment.** Neither party may assign this Agreement without the written consent of the other party.

F. **Entire Agreement.** This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes and cancels all prior agreements between the parties with respect to such subject matter.

**IN WITNESS WHEREOF,** the parties have caused this Telemedicine Credentialing Agreement to be executed as of the Effective Date.

**DISTANT SITE HOSPITAL**

| By: _________________________________ | Name: ______________________________ |
| Title: ______________________________ |                          |

**ORIGINATING SITE HOSPITAL**

| By: _________________________________ | Name: ______________________________ |
| Title: ______________________________ |                          |
EXHIBIT A

Telemedicine Providers

The following Telemedicine Providers have been approved by the Distant Site Hospital to provide Telemedicine Services for the Originating Site Hospital. A Telemedicine Provider may not begin providing Telemedicine Services for the Originating Site Hospital until the Originating Site Hospital has granted clinical privileges in accordance with its medical staff process.

<table>
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<tr>
<th>Name</th>
<th>Credentialed Services</th>
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This Exhibit A shall be updated throughout the term of this Telemedicine Credentialing Agreement as new Telemedicine Providers are approved to perform Telemedicine Services for the Originating Site Hospital or as existing Telemedicine Providers either modify or terminate their privileges to provide Telemedicine Services for the Originating Site Hospital.
An Interpretation of the Opinions of the National Health and Family Planning Commission Regarding the Promotion of the Medical Institution Telemedicine Services

中华人民共和国国家卫生和计划生育委员会 2014-08-29
The National Health and Family Planning Commission of the People’s Republic of China
August 29, 2014

PRESENTED BY:

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I. Background of the draft

Performance of telemedicine services by relying on information technologies is one of the effective ways to improve the level of medical services at the grassroots level and resolve the problem of medical care for members of the public at the grassroots level and in remote areas. Documents including Opinions Regarding the Deepening of the Reforms of the Medical and Health System, The 12th Five-Year Plan for the Development of the Health Cause and Several Opinions of the State Council Regarding the Consumption of Information and Expansion of the Domestic Demand have all set forth clear requirements in this regard.

Since 2010, the financial authorities of the central government have invested ¥84.28 million Yuan, in supporting 22 Midwestern provinces and Xinjiang Production and Construction Corp. in setting up telemedicine systems and in making arrangements for 12 hospitals originally subject to the jurisdiction (control) of the Ministry of Health to set up high-end remote diagnosis systems with 12 Midwestern provinces. A total of 12 hospitals originally subject to the jurisdiction (control) of the Ministry of Health, 98 hospitals at level 3, 3 hospitals at level 2 and 726 county level hospitals have been included, thus giving a vigorous promotion to the development of telemedicine services. Nationwide, the total number of medical institutions performing telemedicine services is 2,057.

In order to utilize the telemedicine services more effectively at the State level, clear provisions are needed for management, regulations, implementing procedures, identifying responsibilities and supervision of telemedicine services to promote their healthy development. The Notice on Reinforcing the Administration of Telemedicine, printed and issued on January 4, 1999 by the former Ministry of Health (Health Office Issue (1999) Number 2), mainly regulates the management of remote diagnosis. With more advanced technologies, the scope of telemedicine services has been greatly expanded. New...
telemedicine service items, such as remote pathological diagnosis, remote imaging diagnosis and remote monitoring, etc., have been used widely. The original managerial requirements no longer meet the actual requirements of the current development in telemedicine services. To promote the sustained healthy development of telemedicine services, optimize the allocation of medical resources and achieve the goal of providing quality medical services resources to the grassroots level, the National Health and Family Planning Commission has prepared the *Opinions Regarding the Promotion of Medical Institution Telemedicine Services* (hereinafter referred to as “The Opinions.”)
《意见》分为4个部分，其主要内容如下：

The Opinions are divided into 4 parts and its major items are as follows:

（一）积极推动远程医疗服务发展。
(i) Actively promote the development of telemedicine services.

地方各级卫生计生行政部门要将远程医疗服务体系建设纳入区域卫生规划和医疗机构设置规划，积极协调同级财政部门为远程医疗服务的发展提供相应的资金支持和经费保障，协调发展改革、物价、人力资源社会保障等相关部门，为远程医疗服务的发展营造适宜的政策环境。

Administrative authorities in charge of health and family planning at various local levels should include the construction of a telemedicine service system in their regional health plan and medical institution setup plan, actively coordinate with financial authorities at the same level in order to provide appropriate funding, support and safeguarding for the development of telemedicine services and coordinate with relevant authorities, including reforms, pricing, human resources and Social Security, etc. in order to create an appropriate policy environment for the development of telemedicine services.

（二）确保远程医疗服务质量安全。
(ii) Ensure the quality and safety of telemedicine services.

一是明确了远程医疗服务的定义和内容：一方医疗机构邀请其他医疗机构，运用通讯、计算机及网络技术，为本医疗机构诊疗患者提供技术支持的医疗活动。其项目主要包括：远程病理诊断、远程医学影像诊断、远程监护、远程会诊、远程门诊、远程病例讨论等。

First, clarify the definition and content of telemedicine services: on one hand, medical institutions invite other medical institutions in using communications, computer and network technologies to provide medical activities in the diagnosis and treatment of patients of their own medical institutions with technical support. Their products mainly include: remote pathological diagnosis, diagnostic imaging monitoring, consultations, outpatient services and case discussions, etc.

二是要求医疗机构在开展远程医疗服务过程中严格遵守相关法律、法规、信息标准和技术规范，确保医疗质量安全，维护患者合法权益。非医疗机构不得开展远程医疗服务。

Second, during the performance of telemedicine services, medical institutions are required to strictly comply with the applicable laws, regulations, information standards and technical practices, ensuring the quality and safety of medical services and protecting the legal interest of patients. Non-medical institutions are not authorized to provide telemedicine services.
（三）完善远程医疗服务流程。
(III) Perfect telemedicine service processes.
一是要求开展远程医疗服务的医疗机构具备相应的诊疗科目及人员、技术、设备、设施条件，签订远程医疗服务合作协议，约定远程医疗服务流程、权利义务、医疗损害风险和责任分担等事项，并取得患者知情同意。
First, medical institutions that perform telemedicine services are required to have appropriate diagnostic and treatment departments, personnel, technologies, equipment facilities, execute telemedicine cooperation agreements and covenant items, including telemedicine service processes, rights and obligations and the sharing of medical harm risks and responsibilities, etc., and obtain the informed consent of patients.

二是要求开展远程医疗服务的医疗机构完善远程医疗服务流程，并认真做好组织实施。医疗机构要按照病历书写及保管有关规定共同完成病历资料。
Second, medical institutions that undertake telemedicine services are required to perfect their telemedicine service processes and conscientiously organize their implementation. Medical institutions should jointly complete medical records information in accordance with the relevant provisions for the writing and safekeeping of medical records.

（四）加强远程医疗服务监督管理。
(IV) Enhance the supervision and management of telemedicine services.
一是要规范机构名称。未经国家卫生计生委核准，任何开展远程医疗服务的医疗机构，不得冠以“中国”、“中华”、“全国”及其他指代、暗含全国或者跨省（自治区、直辖市）含义的名称。
First, standardize names of the institutions. Without the approval of the National Health and Family Planning Commission, no medical institution performing telemedicine services shall include in their names “China,” “Chinese” and “National” and other alternative names or names that imply a nationwide or interprovincial (inter-autonomous regions and cities subject to the direct jurisdiction of the central government) scope.

二是要控制安全风险。医疗机构在开展远程医疗服务过程中，主要专业技术人员或者关键设备、设施及其他辅助条件发生变化，不能满足远程医疗服务需要，或者存在医疗质量和医疗安全隐患，以及出现与远程医疗服务直接相关严重不良后果时，须立即停止远程医疗服务并按规定报告。
Second, safety control risks. During the performance of telemedicine services by medical institutions, any change of key professional and technical personnel or key equipment, facilities and other supporting conditions, which makes it impossible to meet the need for the telemedicine services or if there exists any hazards with the quality of medical services and medical safety and upon the occurrence of serious adverse consequences directly related to telemedicine services, telemedicine services should be stopped immediately and a report shall be filed in accordance with the applicable provisions.

三是要加强日常监管。地方各级卫生计生行政部门在监督检查过程中发现存在远程医疗服务相关的医疗质量安全隐患或者接到相关报告时，要及时组织对医疗机构远程医疗服务条件的论证，经论证不具备远程医疗服务条件的，要提出整改措施，在整改措施落实前不得继续开展远程医疗服务。
Third, strengthening daily supervision. Health and Family Planning administrative departments at all levels shall timely organize the论证 of the conditions of medical institutions for telemedicine services during the process of supervision and inspection. If the论证 indicates that the conditions are incapable of meeting the need for the telemedicine services, measures should be proposed for rectification, and the telemedicine services are not allowed to continue until the rectification measures are implemented.
Third, enhance daily supervision. When administrative authorities at various local levels in charge of health and family planning discover hazards that exist with the quality and safety of medical services related to telemedicine services, they should immediately conduct an investigation, and verification of any issues with proof. Upon such an investigation, if the conditions are not adequately improved to provide telemedicine services, corrective actions should be proposed and prior to the execution of such corrective actions, and telemedicine service is not permitted to continue.

Fourth, handle the matter in accordance with laws and regulations. Upon the occurrence of any medical dispute during the performance of telemedicine services, the host and the invited party shall handle the matter in accordance with the applicable laws and regulations and the agreement reached by and between the parties and undertake the appropriate responsibilities. When medical personnel directly provide telemedicine services to patients, their medical institutions should undertake the appropriate responsibility in accordance with the provisions of applicable laws and regulations. In the event that medical institutions and medical personnel engage in actions that violate laws and regulations during the process of the performance of telemedicine services, the administrative authorities in charge of health and family planning should deal with the same in accordance with the provisions of applicable laws and regulations.

In addition, when information technology is used among medical institutions, whereby one medical institution uses the relevant equipment to precisely control the instruments and equipment (such as a surgical robot) of another medical institution to directly perform medical activities, such as an examination, diagnosis, treatment, real-time operational surgery and monitoring, the management measures and relevant standards and regulations therefore will be separately prepared by our Commission. When telemedicine services are performed between [Chinese] medical institutions and medical institutions outside of our country, reference should be made to The Opinions.

Related link: Opinions of the National Health and Family Commission Regarding the Promotion of Medical Institution Telemedicine Services

[See next page for Attachment translation.]
为推动远程医疗服务持续健康发展，优化医疗资源配置，实现优质医疗资源下沉，提高医疗服务
能力和水平，进一步贯彻落实《中共中央国务院关于深化医药卫生体制改革的意见》，现就推进
医疗机构远程医疗服务提出以下意见：

To promote the sustained and healthy development of telemedicine services, optimize the allocation of
medical resources, achieve the goal of providing quality medical services resources to the grassroots
level, improve the capability and level of medical services and further implement and execute the
Opinions of the Central Committee of the Chinese Communist Party and the State Council regarding the
Deepening of the Reforms of the Medical and Health Systems, the following Opinions are hereby
proposed in the initiative for the improvement of telemedicine services by medical institutions:
一、加强统筹协调，积极推动远程医疗服务发展

I. Enhance overall coordination and actively promote the development of telemedicine services

地方各级卫生计生行政部门要将发展远程医疗服务作为优化医疗资源配置、实现优质医疗资源下沉、建立分级诊疗制度和解决群众看病就医问题的重要手段积极推进。将远程医疗服务体系建设纳入区域卫生规划和医疗机构设置规划，积极协调同级财政部门为远程医疗服务的发展提供相应的资金支持和经费保障，协调发展改革、物价、人力资源社会保障等相关部门，为远程医疗服务的发展营造适宜的政策环境。鼓励各地探索建立基于区域人口健康信息平台的远程医疗服务平

Administrative authorities at various local levels in charge of health and family planning should actively promote the improvement of the quality of telemedicine services as an important means of optimizing the allocation of medical resources, achieve the goal of providing quality medical services resources to the grassroots level, setting up diagnostic and treatment systems at various levels and resolving the issue of medical diagnosis and treatment for members of the public. [Such authorities should also] include construction of a telemedicine service system in their regional health plan and medical institution setup plan, actively coordinate with financial authorities at the same level in order to provide appropriate funding and support and safeguards for the development of telemedicine services and coordinate with [other] relevant authorities, including reforms, pricing, human resources and Social Security, etc., in order to create an appropriate policy environment for the development of telemedicine services. [In addition, they should] encourage various locales to explore the setup of platforms for provision of telemedicine services based on the health information platform of the regional populations.
二、明确服务内容，确保远程医疗服务质量安全

II. Clarify service items and ensure the quality and safety of telemedicine services

(一) 远程医疗服务内容。远程医疗服务是一方医疗机构（以下简称邀请方）邀请其他医疗机构（以下简称受邀方），运用通讯、计算机及网络技术（以下简称信息化技术），为本医疗机构诊疗患者提供技术支持的医疗活动。医疗机构运用信息化技术，向医疗机构外的患者直接提供的诊疗服务，属于远程医疗服务。远程医疗服务项目包括：远程病理诊断、远程医学影像（含影像、超声、核医学、心电图、肌电图、脑电图等）诊断、远程监护、远程会诊、远程门诊、远程病例讨论及省级以上卫生计生行政部门规定的其他项目。

(I) Telemedicine service items. Telemedicine services are medical activities whereby the medical institutions of one party (hereinafter referred to as the host) invite other medical institutions (hereinafter referred to as the invited parties) to use communications, computer and network technologies (hereinafter referred to as information technologies) to provide technical support in the diagnosis and treatment of patients in their own institutions. Diagnostic and treatment services provided by medical institutions using information technologies directly to patients outside their own medical institutions are telemedicine services. Telemedicine service items include: remote pathological diagnosis, remote medical imaging (including imaging, ultrasound, nuclear medicine, electrocardiograms, electromyography and electroencephalograms, etc.) diagnosis, remote monitoring, remote consolidations, remote outpatient services and remote case discussions and other items provided by administrative authorities above the provincial levels in charge of health and family planning.

(二) 遵守相关管理规范。医疗机构在开展远程医疗服务过程中应当严格遵守相关法律、法规、信息标准和技术规范，建立健全远程医疗服务相关的管理制度，完善医疗质量与医疗安全保障措施，确保医疗质量安全，保护患者隐私，维护患者合法权益。非医疗机构不得开展远程医疗服务。

(II) Comply with the relevant management regulations. During the process of the performance of telemedicine services, medical institutions should strictly comply with the applicable laws, regulations, information standards and technical practices, have in place a complete professional management system related to telemedicine services, perfect medical service quality and medical safety safeguards, ensure the quality and safety of medical services and protect the privacy of patients and the legitimate interest of patients. Non-medical institutions are not permitted to perform telemedicine services.
三、完善服务流程，保障远程医疗服务优质高效
III. Perfect the service process and ensure the high quality and efficiency of telemedicine services

(一) 具备基本条件。医疗机构具备与所开展远程医疗服务相适应的诊疗科目及相应的人员、技术和设施条件，可以开展远程医疗服务，并指定专门部门或人员负责远程医疗服务仪器、设备、设施、信息系统的定期检测、登记、维护、改造、升级，确保远程医疗服务系统（硬件和软件）处于正常运行状态，符合远程医疗相关卫生信息标准和信息安全的规定，满足医疗机构开展远程医疗服务的需要。

(I) Possess the basic conditions. Medical institutions have the diagnostic and treatment subjects befitting the performance of telemedicine services and corresponding personnel, technologies, equipment and facilities and conditions, can perform telemedicine services and designate dedicated departments or personnel that are responsible for the regular tests, registrations, maintenance, modifications and upgrades of the instruments, equipment, facilities and information systems used in telemedicine services, to ensure that telemedicine service systems (hardware and software) are in standard operation, meet the relevant health information standards and information security provisions related to telemedicine services and meet the needs for medical institutions in performing their telemedicine services.

(二) 签订合作协议。医疗机构之间开展远程医疗服务的，要签订远程医疗合作协议，约定合作目的、合作条件、合作内容、远程医疗流程、双方权利义务、医疗损害风险和责任分担等事项。

(II) Execute a cooperation agreement. When medical institutions perform telemedicine services among themselves, they should execute a cooperation agreement on telemedicine services and covenant items such as the purpose of a cooperation, conditions of cooperation, processes of telemedicine services, the rights and obligations of the parties and the sharing of the risks of medical harm and responsibilities.

(三) 患者知情同意。邀请方应当向患者充分告知并征得其书面同意，不宜向患者说明的，须征得其监护人或者近亲属书面同意。

(III) Informed consent of patients. The host should fully inform patients and seek their written consent. When it is not appropriate to offer an explanation to the patient [e.g., in minor patient situations], the written consent of the guardian or a close relative of patients should be sought.

(四) 认真组织实施。邀请方需要与受邀方通过远程医疗服务开展个案病例讨论的，需向受邀方提出邀请，邀请至少应当包括邀请事由、目的、时间安排，患者相关病历摘要及拟邀请医师的专业和技术职务任职资格等。受邀方接到远程医疗服务邀请后，要及时作出是否接受邀请的决定。接受邀请的，须告知邀请方，并做好相关准备工作；不接受邀请的，及时告知邀请方并说明理由。

(IV) Conscientiously organize implementation. When the host needs to engage in a discussion of individual cases in the performance of telemedicine services, it needs to submit an invitation to the invited party. The invitation should at least include the cause of action, purpose of the invitation, the schedule, excerpts of the relevant medical records of the patient and the professional and technical
positions and competency qualifications of the physicians proposed for the invitation. After receiving an
invitation for telemedicine services, the invited party should promptly make a decision as to whether to
accept such an invitation. If it accepts such an invitation, it must notify the host and properly perform
the relevant preparatory work; if it does not accept the invitation, it should promptly notify the host and
explain the reasons.

The invited party should conscientiously and responsibly arrange for medical personnel with appropriate
qualifications and technical abilities to provide telemedicine services in accordance with the
requirements of applicable laws, regulations and diagnostic practices, promptly inform the host of the
diagnostic opinions and issue diagnostic opinions and reports signed by the relevant physicians. The host
has the right of medical disposal with respect to the patients and should, based on the clinical
information on the patients and with reference to the diagnostic opinions of the invited party, make
diagnostic and treatment decisions.

(V) Properly maintain records. The host and the invited party should jointly complete medical record
information in accordance with the provisions related to the writing and safekeeping of medical records.
The original copies should be separately filed by the host and invited party respectively. Documents
related to telemedicine services can be sent by fax, scanned and electronically signed for electronic filing.

(VI) Simplify the service process. The host and the invited party should set up matching support or
another kind of partnership relationship. Where the host implements auxiliary examinations and the
invited party issues corresponding auxiliary examination reports, the telemedicine service process
should be covenanted by and between the host and invited party in the telemedicine cooperation
agreement.

(VII) Standardize personnel management. In the event that medical personnel provide telemedicine
services directly to patients outside their own medical institutions, the consent of the medical
institutions where they are registered to practice should be obtained and the information platform
centrally set up by the medical institutions should be used to provide diagnostic and treatment services
for patients.
IV. Enhance supervision and management and guarantee the legitimate interests of both physicians and patients

(I) Standardize names of the institutions. Administrative authorities in charge of family planning should enhance supervision and management of telemedicine services. Without the approval of our Commission, no medical institution performing telemedicine services should include in their name “China,” “Chinese” and “National” and other alternative names or names that imply a nationwide or interprovincial (inter-autonomous regions and cities subject to the direct jurisdiction of the central government) scope.

(II) Control safety risks. During the process of the performance of telemedicine services by medical institutions, in case of any change to key professional and technical personnel or key equipment, facilities and other supporting conditions, which makes it impossible to meet the need for telemedicine services or if there exists any hazards with the quality of medical services and medical safety and upon the occurrence of serious adverse consequences directly related to the telemedicine services, telemedicine services should be stopped immediately and a report should be filed with the administrative authorities in charge of health and family planning that have issued License of a Medical Institution for Practice thereto in accordance with the requirements of Interim Provisions for Reporting Medical Service Quality and Safety Incidents.

(III) Enhance daily supervision. When administrative authorities at various local levels in charge of health and family planning discover hazards that exist with the quality and safety of medical services related to telemedicine services, they should immediately organize an investigation and verification with proof by medical institutions. Upon such an investigation, if the conditions are not adequately improved to provide telemedicine services, corrective actions should be proposed and prior to the execution of such corrective actions, performance of telemedicine services should not continue.
（四）依法依规处理。在远程医疗服务过程中发生医疗争议时，由邀请方和受邀方按照相关法律、法规和双方达成的协议进行处理，并承担相应的责任。医务人员直接向患者提供远程医疗服务的，由其所在医疗机构按照相关法律、法规规定，承担相应责任。医疗机构和医务人员在开展远程医疗服务过程中，有违反《执业医师法》、《医疗机构管理条例》、《医疗事故处理条例》和《护士条例》等法律、法规行为的，由卫生计生行政部门按照有关法律、法规规定处理。

(IV) Handle the matter in accordance with laws and regulations. Upon the occurrence of any medical dispute during the performance of telemedicine services, the host and the invited parties should handle the matter in accordance with the applicable laws and regulations and the agreement concluded by and between the parties and undertake appropriate responsibilities. When medical personnel directly provide telemedicine services to patients, their medical institutions should undertake appropriate responsibility in accordance with the provisions of applicable laws and regulations. In the event that medical institutions and medical personnel engage in actions that violate laws and regulations, including the Law of Practicing Physicians, Management Regulations of Medical Institutions, Regulations for the Handling of Medical Accidents and Nurse Regulations, etc., during the process of the performance of telemedicine services, the administrative authorities in charge of health and family planning should deal with the same in accordance with the provisions of applicable laws and regulations.

医疗机构之间运用信息化技术，在一方医疗机构使用相关设备，精确控制另一方医疗机构的仪器设备（如手术机器人）直接为患者进行实时操作性的检查、诊断、治疗、手术、监护等医疗活动，其管理办法和相关标准规范由我委另行制定。医疗机构与境外医疗机构之间开展远程医疗服务的，参照本意见执行。执行过程中有关问题，请及时与我委医政医管局联系。

When information technology is used among medical institutions, whereby one medical institution uses the relevant equipment to precisely control the instruments and equipment (such as a surgical robot) of another medical institution to directly perform medical activities, such as examination, diagnosis, treatment, real-time operational surgery and monitoring, the management measures and relevant standards and regulations therefore will be separately prepared by our Commission. When telemedicine services are performed between medical institutions and medical institutions outside our country, reference should be made to The Opinions. For any issue during the implementation process, please contact Medical Administration and Medical Control Bureau of our Commission in a timely manner.

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国家卫生计生委

National Health and Family Planning Commission

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2014 Telemedicine Survey
Executive Summary
November 2014
As health care executives transform operations to comply with the Affordable Care Act, they are gearing up for the next monumental shift in the industry: telemedicine.

Technology has influenced nearly every sector of the economy, and the health care industry is following suit. Among telemedicine’s many benefits are the potential to exponentially expand a provider’s geographic footprint, use doctors’ time more efficiently and dramatically reduce the barriers to patient interaction.

Health care leaders tell us that their organizations are committed to continuing to implement telemedicine programs, even as they face challenges such as getting doctors to buy into the programs and insurers to pay for them. Why? For the majority of respondents, it’s simple — they believe telemedicine will help them keep patients healthier.

This report is based on feedback from health care leaders, the majority of whom are C-level executives from for-profit and nonprofit care providers, including hospitals, home health organizations and physician group practices. We asked them to evaluate the prospects for improved patient care and streamlined operations through telemedicine advancements, as well as regulatory hurdles and obstacles to reimbursement.

**Executives Are Embracing Telemedicine**

Telemedicine is not a distant possibility; it is here and in play now. The vast majority of leaders (90 percent) report that their organizations have already begun developing or implementing a telemedicine program. Most also say that offering meaningful telemedicine services will be critical to the future success of their organizations.

» Eighty-four (84) percent of respondents felt that the development of telemedicine services is either very important (52 percent) or important (32 percent) to their organizations. Virtually none said they considered the technology to be unimportant (3 percent).

» While just 6 percent of respondents categorized their telemedicine programs as “mature,” only 8 percent said they had none at all. The remainders of responses are clustered somewhere in the middle: 34 percent are under consideration or in development, 18 percent are in the optimization phase, and the remaining 36 percent are being piloted or implemented.

» A majority of respondents already offer remote monitoring (64 percent), store and forward technology (54 percent), and real-time interaction capabilities (52 percent). Additionally, 39 percent say they have services that qualify as mHealth — patient-driven apps and online portals.
The Affordable Care Act Is Driving Telemedicine Advancements

This attitude is partly due to the shift in financial and payment incentives under the ACA. As health care providers move from a fee-for-service model to one that reimburses based on positive patient outcomes, providers bear a greater share of the risk — and potential reward — for keeping their patients healthy. In addition, the level of responsibility shifts even more for providers in risk-bearing contracts or capitated arrangements, in which payments are made per person rather than per service. For executives under pressure to find cost-effective methods of engagement with their patients, telemedicine offers ways to streamline operations and create multiple touch points with patients, making it one of the most reliable methods for transitioning to a post-ACA, forward-looking reimbursement model.

» Executives are most excited about telemedicine’s potential to keep patients healthier. Half of respondents (50 percent) ranked improving the quality of care as their number one rationale for implementing telemedicine. Another 18 percent were most excited about reaching new patients.

» Despite the cost savings tied to telemedicine, health care leaders do not expect an immediate economic return on investment. A minimal percentage of respondents ranked the potential for increased revenue/profitability (11 percent) and getting a jump on the competition (4 percent) as their top motivators.

Reimbursement Is the Primary Obstacle to Implementation

Although leaders fully endorsed the robust prospects of telemedicine, they were less confident about its immediate adoption. The widespread use of telemedicine requires doctors to be willing to transform the look and feel of the traditional, in-person patient visit. Meanwhile, the customary fee-for-service environment makes it challenging to be paid for medicine practiced outside the traditional spheres of interaction.

» Being paid for telemedicine remains an uphill battle, as indicated by 41 percent of respondents who said they are not reimbursed at all for telemedicine services, and 21 percent who reported receiving lower rates from managed care companies for telemedicine than for in-person care.

» Aside from reimbursement challenges, 48 percent of executives say they are more concerned with convincing doctors about the credibility of telemedicine than they are with convincing doctors that they will be adequately compensated for practicing it (36 percent).

» This uncertain environment led 87 percent of respondents to report that they do not believe a majority of their patients will be using any of their organization’s telemedicine services three years from now. Almost one-quarter said they anticipated fewer than 10 percent of their patients utilizing their organization’s services.
Executives Are Embracing Telemedicine

Overwhelmingly, 84 percent of respondents indicated that the development of telemedicine services is either very important (52 percent) or important (32 percent) to their organizations. With this in mind, most are already piloting some suite of telemedicine products and more than half have developed some set of standards and guidelines to steer the implementation of services. A majority of respondents already offer remote monitoring (64 percent), store and forward technology (54 percent) and real-time interaction capabilities (52 percent).

Why do such a large majority of executives believe that the future success of their organizations is tied in part to telemedicine? From dramatically increasing a specialist’s geographic footprint to enabling chronic care management outside the hospital, telemedicine can transform an industry that is ripe for disruption. Nearly every other arena of the economy has been reshaped by technology, and medicine is catching the drift.
This excitement is reflected in a venture capital market whose interest in telemedicine technologies has grown significantly in recent years, including a $50 million funding round by eVisit firm Teladoc in September 2014. Teladoc’s competitor Doctor on Demand raised $21 million in August 2014. According to Mercom Capital Group, since 2010, the two quarters with the largest amount of funding raised for health care IT — a term synonymous with telemedicine — were Q2 and Q3 of 2014.

Indeed, many Americans already participate in telemedicine in ways they may not recognize. This gradual adoption is already enabling executives to embark on more ambitious projects that embrace technologies in ways less familiar to patients and doctors, such as teleconferencing between patient and provider. Deloitte predicts that in 2014, there will be as many as 75 million such visits in North America. As with all technologies, executives appear to think the growth curve is more likely to be exponential than linear.
The Affordable Care Act Is Driving Telemedicine Advancements

In the wake of the ACA, an ounce of prevention is now truly worth — in American dollars — a pound of cure. Models like capitation, in which a provider receives a flat fee per patient, and bundled payments, in which patients pay a one-time charge for a procedure, are moving out of the margins and into the mainstream.

Because the ACA penalizes hospitals for excessive numbers of readmissions and hospital-acquired conditions, health care executives are more focused on keeping their patients healthy, a priority supported by their primary reasons for implementing telemedicine services. When given a list of six possible motivations for adopting telemedicine, a full half of respondents said the improvement of the quality of care for patients was their number one rationale.

With its ability to multiply patient points of contact at a significantly reduced cost, telemedicine enables physicians to keep closer tabs on their patients, whether it is monitoring blood pressure from a distance or ensuring day-to-day medication adherence. That is a primary reason why almost two-thirds of respondents said they already had remote monitoring programs in place, which allow providers to gather vital patient information and provide chronic care management remotely.

Simultaneously, telemedicine lowers the barriers to entry for patients to receive advice and support from medical professionals. The rural, the homebound and the elderly no longer have to make the trip to the office, and national experts can now weigh in on the maladies of patients from out of state using remote consultations. Executives charged with delivering both financial sustainability and their organizations’ social mission see these benefits and consequently embrace the patient-centered opportunities that telemedicine provides.
Reimbursement Is the Primary Obstacle to Implementation

When it comes to the spread of telemedicine, there remains a gulf between the aspirations and the regulatory environment. Even as the vast majority of executives endorse telemedicine as an important part of their future, 87 percent of respondents do not think the majority of their patients will be using their organizations’ telemedicine services three years from now, and almost a quarter say fewer than one in 10 patients will. There are a host of reasons for these concerns, but three stick out: trouble with reimbursement, a lack of physician buy-in and a regulatory landscape that is erratic at best.

Respondents were most disheartened by the difficulties of seeking and receiving reimbursement, with approximately half identifying these troubles as their primary obstacle to implementation. The reality corresponds to the sentiment, as 41 percent said their organizations receive no reimbursement for a telemedicine visit. Another one in five said they received lower rates for telemedicine than in-person care from managed care companies.

Nor was the government’s rate of reimbursement sufficient to incentivize executives to roll out telemedicine on a broader scale. One in five indicated that Medicare’s thin coverage practices for telemedicine was their biggest reimbursement concern; 18 percent said they were most uneasy about state laws failing to mandate that commercial coverage companies pay for telemedicine services. Compounding these concerns are several restrictions that fuel the pessimistic outlook respondents harbor. Primary among them is the requirement that a provider obtain licensure in whatever state he or she provides telemedicine services. Internal concerns abound as well, from the need to amend existing corporate structures to the necessity of building supervisory structures that will mitigate the potential for fraud and abuse.
The medical boards of Georgia and Florida are the latest to provide a set of guidelines for the practice of responsible telemedicine. In September 2014, California enacted a law that loosened the consent requirements for practicing telemedicine. However, the ultimate solution for both a legal and reimbursement framework will likely be a federal one. There is hope in Washington: According to the American Telemedicine Association, there are 55 pieces of legislation pending that will address telemedicine in one way or another. The most comprehensive of these, the Medicare Telehealth Parity Act, was introduced this summer.

Physicians have a reputation for being slow adopters to new avenues of care — particularly to those that they see as untested. Our survey shows that telemedicine is no different. Almost half of those surveyed worried that physicians would not regard telemedicine as a credible and high-quality supplement to their practice. Given the visceral differences between palpating a patient in the examination room and chatting about symptoms through a laptop camera, health care providers will have to work to make their doctors comfortable with new technology.
Questions about reimbursement and physician support do a lot to account for why half of respondents reported that their telemedicine programs were in the earliest stages — 34 percent that were still pre-operational, with 16 percent in the pilot phase.
Methodology and Demographics

Foley distributed the 2014 Telemedicine Survey to health care executives throughout the United States in September and October 2014. The survey was completed by 57 executives, and results were tabulated, analyzed and released in November 2014.

Respondents
» C-suite executives – 34 percent
» Director, vice president, or manager – 34 percent
» Administrator – 11 percent
» In-house attorneys/corporate counsel – 11 percent
» Other professionals – 10 percent

Health Care Organizations — Types
» Non-profit hospitals – 44 percent
» Provider groups – 13 percent
» Long-term care management – 11 percent
» For-profit hospitals – 8 percent
» Physician group practices – 6 percent
» Managed care – 4 percent
» Municipal hospitals – 4 percent
» Other (medical assistance, service provider and etc.) – 10 percent

Health Care Organizations — Size
» More than 10,000 full-time employees – 19 percent
» More than 1,000 full-time employees – 28 percent
» Between 501 – 1,000 full-time employees – 20 percent
» Between 101 – 500 full-time employees – 11 percent
» Between 1 – 100 full-time employees – 22 percent

For More Information
To learn more about Foley’s Telemedicine Survey, please contact Linda Yun at 312.832.4755 or lyun@foley.com, or Ashley Hutchinson at 312.832.5789 or ahutchinson@foley.com.
MODEL POLICY FOR THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE

Report of the State Medical Boards’ Appropriate Regulation of Telemedicine (SMART) Workgroup

INTRODUCTION

The Federation of State Medical Boards (FSMB) Chair, Jon V. Thomas, MD, MBA, appointed the State Medical Boards’ Appropriate Regulation of Telemedicine (SMART) Workgroup to review the “Model Guidelines for the Appropriate Use of the Internet in Medical Practice” (HOD 2002)¹ and other existing FSMB policies on telemedicine and to offer recommendations to state medical and osteopathic boards (hereinafter referred to as “medical boards” and/or “boards”) based on a thorough review of recent advances in technology and the appropriate balance between enabling access to care while ensuring patient safety. The Workgroup was charged with guiding the development of model guidelines for use by state medical boards in evaluating the appropriateness of care as related to the use of telemedicine, or the practice of medicine using electronic communication, information technology or other means, between a physician in one location and a patient in another location with or without an intervening health care provider.

This new policy document provides guidance to state medical boards for regulating the use of telemedicine technologies in the practice of medicine and educates licensees as to the appropriate standards of care in the delivery of medical services directly to patients² via telemedicine technologies. It is the intent of the SMART Workgroup to offer a model policy for use by state medical boards in order to remove regulatory barriers to widespread appropriate adoption of telemedicine technologies for delivering care while ensuring the public health and safety.

In developing the guidelines that follow, the Workgroup conducted a comprehensive review of telemedicine technologies currently in use and proposed/recommended standards of care, as well as identified and considered existing standards of care applicable to telemedicine developed and implemented by several state medical boards.

¹ The policy on the Appropriate Use of Telemedicine Technologies in the Practice of Medicine supersedes the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (HOD 2002).

² The policy does not apply to the use of telemedicine when solely providing consulting services to another physician who maintains the physician-patient relationship with the patient, the subject of the consultation.
MODEL POLICY FOR THE APPROPRIATE USE OF TELEMEDIATECNE TECHNOLOGIES IN THE PRACTICE OF MEDICINE

Model Guidelines for State Medical Boards’ Appropriate Regulation of Telemedicine

Section One. Preamble

The advancements and continued development of medical and communications technology have had a profound impact on the practice of medicine and offer opportunities for improving the delivery and accessibility of health care, particularly in the area of telemedicine, which is the practice of medicine using electronic communication, information technology or other means of interaction between a licensee in one location and a patient in another location with or without an intervening healthcare provider. However, state medical boards, in fulfilling their duty to protect the public, face complex regulatory challenges and patient safety concerns in adapting regulations and standards historically intended for the in-person provision of medical care to new delivery models involving telemedicine technologies, including but not limited to: 1) determining when a physician-patient relationship is established; 2) assuring privacy of patient data; 3) guaranteeing proper evaluation and treatment of the patient; and 4) limiting the prescribing and dispensing of certain medications.

The [Name of Board] recognizes that using telemedicine technologies in the delivery of medical services offers potential benefits in the provision of medical care. The appropriate application of these technologies can enhance medical care by facilitating communication with physicians and their patients or other health care providers, including prescribing medication, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information, and clarifying medical advice.

These guidelines should not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law. In fact, these guidelines support a consistent standard of care and scope of practice notwithstanding the delivery tool or business method in enabling Physician-to-Patient communications. For clarity, 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 and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of telemedicine technologies as a component of, or in lieu of, in-person provision of medical care, while others are not.

The Board has developed these guidelines to educate licensees as to the appropriate use of telemedicine technologies in the practice of medicine. The [Name of Board] is committed to assuring patient access to the convenience and benefits afforded by telemedicine technologies, while promoting the responsible practice of medicine by physicians.

It is the expectation of the Board that physicians who provide medical care, electronically or otherwise, maintain the highest degree of professionalism and should:

- Place the welfare of patients first;
- Maintain acceptable and appropriate standards of practice;

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4 Id.

MODEL POLICY FOR THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE

- Adhere to recognized ethical codes governing the medical profession;
- Properly supervise non-physician clinicians; and
- Protect patient confidentiality.

Section Two. Establishing the Physician-Patient Relationship

The health and well-being of patients depends upon a collaborative effort between the physician and patient. The relationship between the physician and patient is complex and is based on the mutual understanding of the shared responsibility for the patient’s health care. Although the Board recognizes that it may be difficult in some circumstances to precisely define the beginning of the physician-patient relationship, particularly when the physician and patient are in separate locations, it tends to begin when an individual with a health-related matter seeks assistance from a physician who may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient, and the patient agrees to be treated, whether or not there has been an encounter in person between the physician (or other appropriately supervised health care practitioner) and patient.

The physician-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that physicians recognize the obligations, responsibilities, and patient rights associated with establishing and maintaining a physician-patient relationship. A physician is discouraged from rendering medical advice and/or care using telemedicine technologies without (1) fully verifying and authenticating the location and, to the extent possible, identifying the requesting patient; (2) disclosing and validating the provider’s identity and applicable credential(s); and (3) obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine technologies. An appropriate physician-patient relationship has not been established when the identity of the physician may be unknown to the patient. Where appropriate, a patient must be able to select an identified physician for telemedicine services and not be assigned to a physician at random.

Section Three. Definitions

For the purpose of these guidelines, the following definitions apply:

“Telemedicine” means the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare delivery by replicating the interaction of a traditional, encounter in person between a provider and a patient.

“Telemedicine Technologies” means technologies and devices enabling secure electronic communications and information exchange between a licensee in one location and a patient in another location with or without an intervening healthcare provider.

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7 See Ctel.
Section Four. Guidelines for the Appropriate Use of Telemedicine Technologies in Medical Practice

The [Name of Board] has adopted the following guidelines for physicians utilizing telemedicine technologies in the delivery of patient care, regardless of an existing physician-patient relationship prior to an encounter:

Licensure:
A physician must be licensed, or under the jurisdiction, of the medical board of the state where the patient is located. The practice of medicine occurs where the patient is located at the time telemedicine technologies are used. Physicians who treat or prescribe through online services sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients receive care.8

Establishment of a Physician-Patient Relationship:
Where an existing physician-patient relationship is not present, a physician must take appropriate steps to establish a physician-patient relationship consistent with the guidelines identified in Section Two, and, while each circumstance is unique, such physician-patient relationships may be established using telemedicine technologies provided the standard of care is met.

Evaluation and Treatment of the Patient:
A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (encounter in person) settings. Treatment, including issuing a prescription based solely on an online questionnaire, does not constitute an acceptable standard of care.

Informed Consent:
Evidence documenting appropriate patient informed consent for the use of telemedicine technologies must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following terms:

- Identification of the patient, the physician and the physician’s credentials;
- Types of transmissions permitted using telemedicine technologies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- The patient agrees that the physician determines whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- Hold harmless clause for information lost due to technical failures; and
- Requirement for express patient consent to forward patient-identifiable information to a third party.

Continuity of Care:
Patients should be able to seek, with relative ease, follow-up care or information from the physician [or physician’s designee] who conducts an encounter using telemedicine technologies. Physicians solely providing services using telemedicine technologies with no existing physician-patient relationship prior to the encounter must make documentation of the encounter using telemedicine technologies easily available to the patient, and subject to the patient’s consent, any identified care provider of the patient immediately after the encounter.

Referrals for Emergency Services:
An emergency plan is required and must be provided by the physician to the patient when the care provided using telemedicine technologies indicates that a referral to an acute care facility or ER for treatment is necessary for the safety of the patient. The emergency plan should include a formal, written protocol appropriate to the services being rendered via telemedicine technologies.

Medical Records:
The medical record should include, if applicable, copies of all patient-related electronic communications, including patient-physician communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telemedicine technologies. Informed consents obtained in connection with an encounter involving telemedicine technologies should also be filed in the medical record. The patient record established during the use of telemedicine technologies must be accessible and documented for both the physician and the patient, consistent with all established laws and regulations governing patient healthcare records.

Privacy and Security of Patient Records & Exchange of Information:
Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy, including compliance with the Health Insurance Portability and Accountability Act (HIPAA) and state privacy, confidentiality, security, and medical retention rules. Physicians are referred to “Standards for Privacy of Individually Identifiable Health Information,” issued by the Department of Health and Human Services (HHS). Guidance documents are available on the HHS Office for Civil Rights Web site at: www.hhs.gov/ocr/hipaa.

Written policies and procedures should be maintained at the same standard as traditional face-to-face encounters for documentation, maintenance, and transmission of the records of the encounter using telemedicine technologies. Such policies and procedures should address (1) privacy, (2) health-care personnel (in addition to the physician addressee) 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, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Sufficient privacy and security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions, and laboratory

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results must be secure within existing technology (i.e. password protected, encrypted electronic prescriptions, or other reliable authentication techniques). All patient-physician e-mail, as well as other patient-related electronic communications, should be stored and filed in the patient’s medical record, consistent with traditional record-keeping policies and procedures.

Disclosures and Functionality on Online Services Making Available Telemedicine Technologies:
Online services used by physicians providing medical services using telemedicine technologies should clearly disclose:

- Specific services provided;
- Contact information for physician;
- Licensure and qualifications of physician(s) and associated physicians;
- Fees for services and how payment is to be made;
- Financial interests, other than fees charged, in any information, products, or services provided by a physician;
- Appropriate uses and limitations of the site, including emergency health situations;
- Uses and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies;
- To whom patient health information may be disclosed and for what purpose;
- Rights of patients with respect to patient health information; and
- Information collected and any passive tracking mechanisms utilized.

Online services used by physicians providing medical services using telemedicine technologies should provide patients a clear mechanism to:

- Access, supplement and amend patient-provided personal health information;
- Provide feedback regarding the site and the quality of information and services; and
- Register complaints, including information regarding filing a complaint with the applicable state medical and osteopathic board(s).

Online services must have accurate and transparent information about the website owner/operator, location, and contact information, including a domain name that accurately reflects the identity.

Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits, or incentives (other than the fees for the medical care services) is prohibited. Notwithstanding, online services may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of preferred relationships with any pharmacy is prohibited. Physicians shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit form that pharmacy.
Prescribing:
Telemedicine technologies, where prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination. Such measures should guarantee that the identity of the patient and provider is clearly established and that detailed documentation for the clinical evaluation and resulting prescription is both enforced and independently kept. Measures to assure informed, accurate, and error prevention prescribing practices (e.g., integration with e-Prescription systems) are encouraged. To further assure patient safety in the absence of physical examination, telemedicine technologies should limit medication formularies to ones that are deemed safe by [Name of Board].

Prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician. The indication, appropriateness, and safety considerations for each telemedicine visit prescription must be evaluated by the physician in accordance with current standards of practice and consequently carry the same professional accountability as prescriptions delivered during an encounter in person. However, where such measures are upheld, and the appropriate clinical consideration is carried out and documented, physicians may exercise their judgment and prescribe medications as part of telemedicine encounters.

Section Five. Parity of Professional and Ethical Standards
Physicians are encouraged to comply with nationally recognized health online service standards and codes of ethics, such as those promulgated by the American Medical Association, American Osteopathic Association, Health Ethics Initiative 2000, Health on the Net and the American Accreditation HealthCare Commission (URAC). There should be parity of ethical and professional standards applied to all aspects of a physician’s practice. A physician’s professional discretion as to the diagnoses, scope of care, or treatment should not be limited or influenced by non-clinical considerations of telemedicine technologies, and physician remuneration or treatment recommendations should not be materially based on the delivery of patient-desired outcomes (i.e., a prescription or referral) or the utilization of telemedicine technologies.