

Telehealth Compliance Checklist

*SAMPLE CHECKLIST ONLY – FOR EDUCATIONAL PURPOSES/
DOES NOT CONSTITUTE LEGAL ADVICE*

Professionals

- Are the telehealth professionals licensed in the state where patient located?
- Are there practice standards for patient examinations and remote prescribing?
- Are professionals documenting and maintaining patient records of the encounters?
- Does insurance policy cover telehealth services?
- Is 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?
- Is the telehealth service provider located internationally?

Commercial Insurance, Medicare Advantage, and Medicaid Managed Care

- Does the state require commercial coverage of services provided via telehealth?
- Does the provider's contracts reflect said coverage and include negotiated payment amounts?
- Has reimbursement 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 it recognize patient freedom of choice?

Fraud & Abuse

- If Medicare/Medicaid, does the arrangement comply with the federal Anti-Kickback Statute? (Check provider/vendor arrangements and patient incentive programs)
- If Medicare/Medicaid, does the arrangement comply with the federal Civil Monetary Penalties Law? (Check

provider/vendor arrangements and patient incentive programs)

- Does the arrangement comply with the Stark Law? (Check all physician benefits, including software and equipment tech, to ensure they meet a Stark exception)
- 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 not just where the brick and mortar facility is located, but 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 the elements?
- Does the hospital relying on proxy credentialing have such provisions in its bylaws?
- Is the hospital engaging in periodic re-credentialing assessments and reporting?

Privacy & Security

- Are there privacy and security protocols for the telehealth offerings?

For More Information

Learn more about how we can help you with telemedicine compliance matters. Please contact your Foley attorney or the following:

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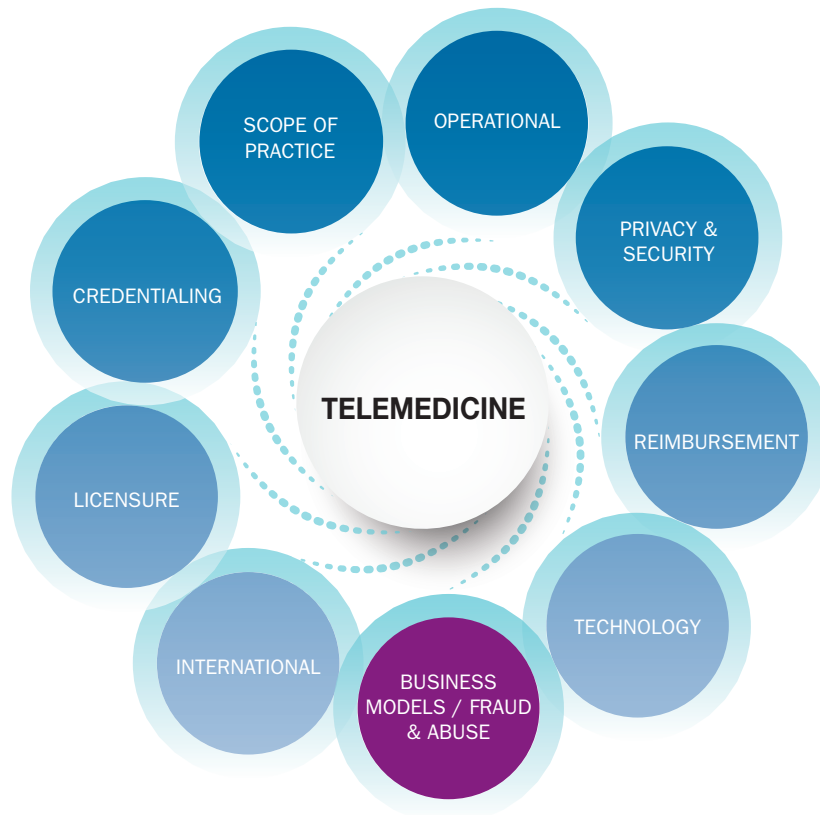
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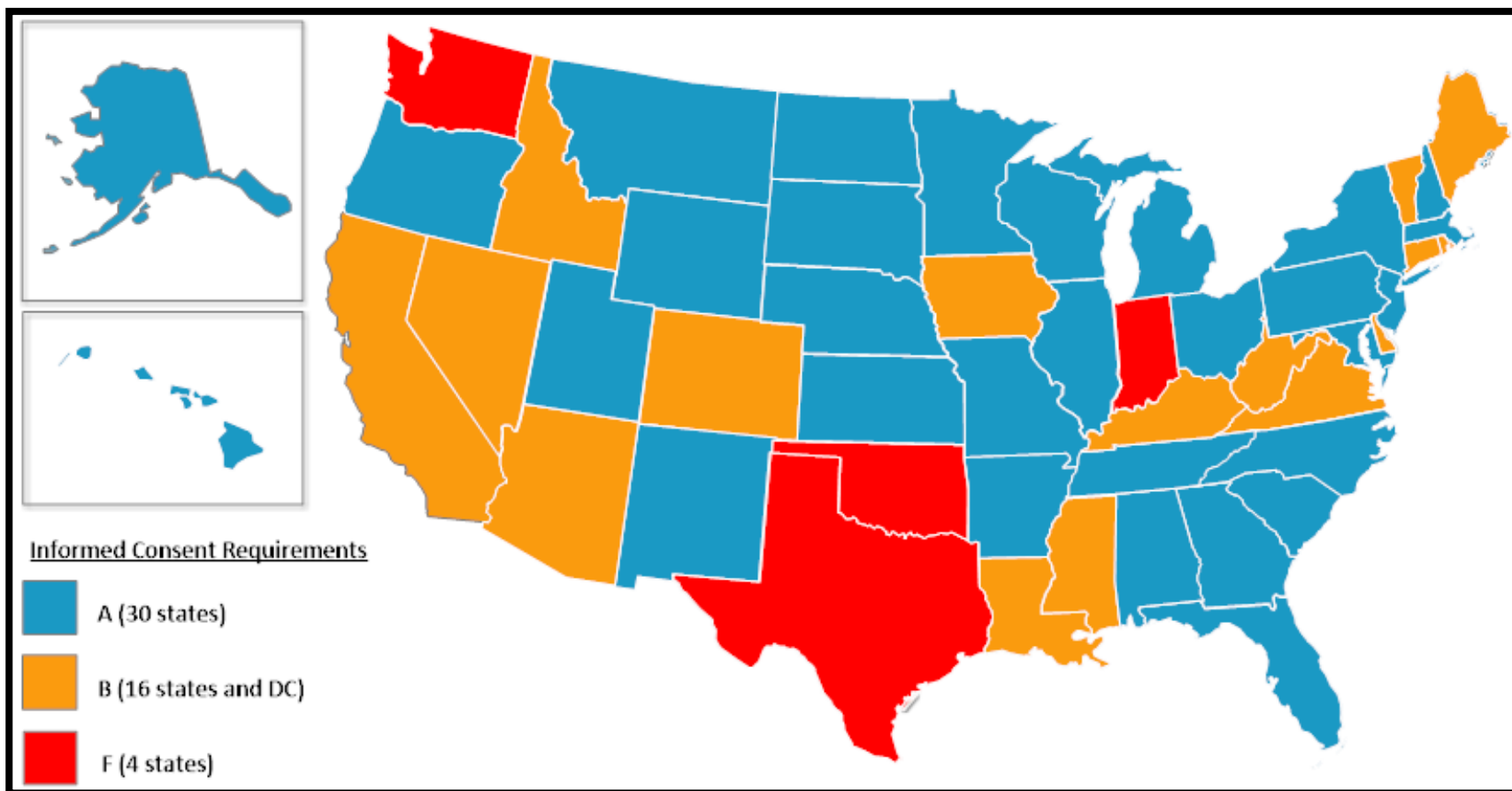
Telemedicine Business and Legal Considerations



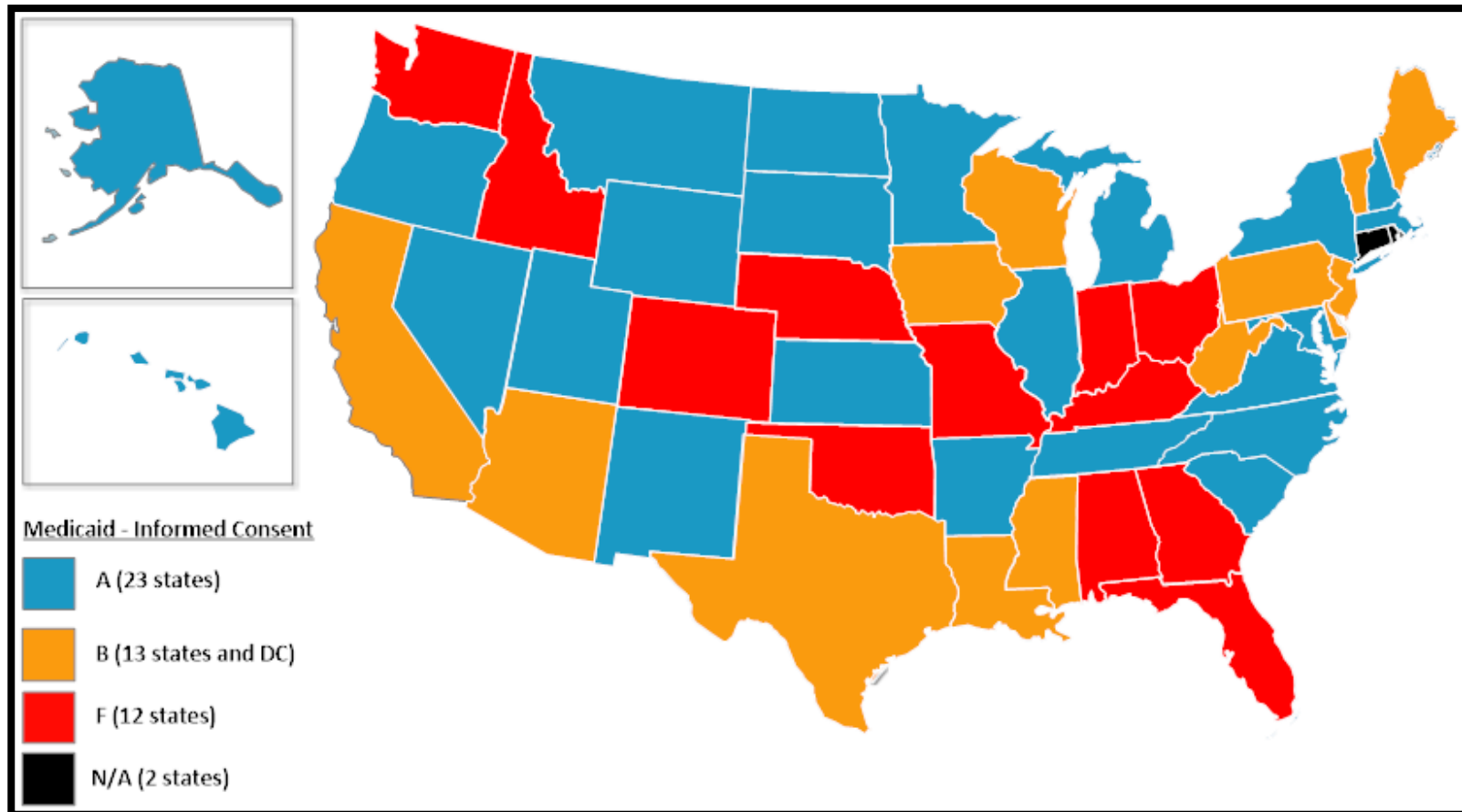
Sample Business Models and Provider Arrangements

- 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
- 4 **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
- 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

State Ratings – Informed Consent Requirements



State Ratings – Medicaid Informed Consent



TELEMEDICINE CREDENTIALING AGREEMENT

THIS TELEMEDICINE CREDENTIALING AGREEMENT is entered into and effective as of the ___ day of _____, 201__ (“Effective Date”), by and between _____ (“Service Provider”), and _____ (“Service Recipient”).

WHEREAS, Service Provider is a Medicare-participating acute care hospital in the State of _____; and

WHEREAS, Service Recipient is a Medicare-participating critical access hospital in the State of _____; and

WHEREAS, Service Recipient desires to engage Service Provider to provide certain health care services via telemedicine, and the parties have entered into a Telemedicine Professional Services Agreement dated _____ to that effect; and

WHEREAS, the parties desire to ease the burdensome credentialing and privileging process relating to telemedicine providers by establishing a telemedicine credentialing and privileging process that meets 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 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, namely Service Recipient’s location.
- D. “Distant Site” means the hospital at which Telemedicine Providers have been granted clinical privileges to perform Telemedicine Services, namely Service Provider’s location.

- E. “Telemedicine Provider” means a duly qualified, credentialed and privileged health care professional who holds a license issued or recognized by the State where the Originating Site is located, and is employed by or under contract with Service Provider to provide Telemedicine Services.
- F. “Telemedicine Services” means the clinical services provided by Telemedicine Providers, under the Telemedicine Professional Services Agreement, to patients at the Originating Site via telemedicine technologies.

II. Service Provider Responsibilities:

- A. Compliance with Conditions of Participation and TJC Standards. Service Provider is a Medicare-participating hospital. Service Provider’s Credentialing Program has been reviewed and approved by its governing body, and meets or exceeds 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. § 485.616(c)(1) through (c)(1)(vii), 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. Specifically, the governing body of the Service Provider Distant Site, through its Credentialing Program, shall:
- a. Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;
 - b. Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;
 - c. Assure that the medical staff has bylaws;
 - d. Approve medical staff bylaws and other medical staff rules and regulations;
 - e. Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;
 - f. Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and
 - g. Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.
- B. Credentialing. Service Provider shall evaluate and, if appropriate, approve privileges and credentialing applications for practitioners at Service Provider who may provide Telemedicine Services.
- a. Service Provider shall provide to Service Recipient a current list of privileges for each Telemedicine Provider who is seeking or has obtained telemedicine privileges at Service Recipient.



- b. Upon reasonable request and subject to State law limitations, Service Provider shall provide Service Recipient with a copy of its bylaws and medical staff rules and policies related to credentialing and peer review, as reasonable evidence of Service Provider's compliance with Section II(A), above.
 - c. Upon reasonable request and subject to State law limitations, Service Provider shall provide Service Recipient with the complete credentialing and privileging file for each Telemedicine Provider who is covered by this Telemedicine Credentialing Agreement.
- C. Recredentialing. Service Provider shall conduct recredentialing 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 recredentialing process information provided to Service Provider by Service Recipient.
- D. Changes in Privileges; Disciplinary Action. Service Provider shall notify Service Recipient as soon as reasonably practicable of any change in privileges of a Telemedicine Provider who is providing Telemedicine Services to Service Recipient, and shall notify Service Recipient of any action classified as disciplinary action under applicable Service Provider policies taken against a Telemedicine Provider.

III. Service Recipient Responsibilities:

- A. Credentialing by Proxy. The governing body and the medical staff of Service Recipient may choose to rely upon Service Provider's Credentialing Program decisions when making its own credentialing and privileging decisions regarding the Telemedicine Providers. To that end, the governing body of Service Recipient shall ensure compliance with the requirements at 42 C.F.R. § 485.616(c)(2) and Standards LD.04.03.09 of TJC's Comprehensive Accreditation Manual for Hospitals. Service Recipient shall ensure that each Telemedicine Provider holds a license issued or recognized by the State where the Originating Site is located. Service Recipient shall ensure the privileges it grants each Telemedicine Provider at Originating Site do not exceed the privileges granted to that Telemedicine Provider at Service Provider.
- B. Originating Site Performance Information. Service Recipient shall maintain evidence of its internal reviews of each Telemedicine Provider's performance and quality at Originating Site and shall provide such performance and quality information to Service Provider for Service Provider's periodic appraisals of the Telemedicine Providers, in accordance with 42 C.F.R. § 485.616(c)(2)(iv). 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 Service



Recipient's patients and all complaints Service Recipient has received about each Telemedicine Provider (including but not limited to adverse outcomes related to sentinel events that are considered reviewable by TJC). Service Recipient shall notify Service Provider as soon as reasonably practicable of any action taken against a Telemedicine Provider by Service Recipient which is classified as disciplinary under Service Recipient's credentialing policies.

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

IV. 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 Service Recipient and Service Provider.

V. 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 ___ () days' prior written notice to the other party, which notice shall specify the effective date of termination.
- b. Mutual Consent. The parties may terminate this Telemedicine Credentialing Agreement at any time by mutual written consent of both parties.
- c. Automatic Termination. In the event the parties' Telemedicine Professional Services Agreement terminates, expires or otherwise ceases, this Telemedicine Credentialing Agreement shall automatically and concurrently terminate.

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

SERVICE PROVIDER**SERVICE RECIPIENT**

By: _____
 Name: _____
 Title: _____

By: _____
 Name: _____
 Title: _____



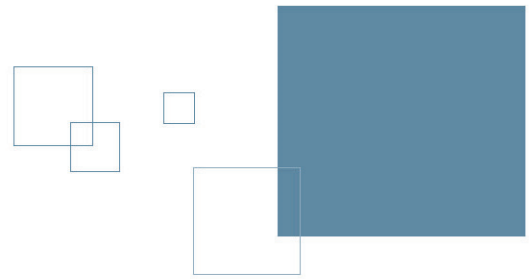
EXHIBIT A**Telemedicine Providers**

The following Telemedicine Providers have been assigned to provide Telemedicine Services for Service Recipient. A Telemedicine Provider may not begin providing Telemedicine Services for Service Recipient until Service Recipient has granted clinical privileges in accordance with its medical staff process.

Name	Credentialed Services

This Exhibit A shall be updated throughout the term of this Telemedicine Credentialing Agreement as new Telemedicine Providers are engaged by Service Provider to perform Telemedicine Services for Service Recipient or as existing Telemedicine Providers terminate their engagement with Service Provider or no longer perform Telemedicine Services for Service Recipient.





Telemedicine Insurance Coverage

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A company offering telemedicine-based services can take steps to ensure it will have meaningful malpractice coverage for its services:

Select a carrier that offers a well-defined and thoughtful telemedicine malpractice coverage product.

Under some policies, the carrier retains the right to selectively deny coverage.

Common reasons for selective denial of coverage include:

- The patient or service provided is not located in a state where the insurance company is licensed
- The physician/exposure presents an above-average risk
- Coverage disallows telemedicine direct patient care, but does allow peer-to-peer physician consultations

Ensure the policy extends coverage to all the states where the provider wants to provide services.

Ensure the malpractice carrier itself is licensed in all the states where the provider wants to provide telemedicine services (i.e., where the patients are located).

Keep in mind: insurance is regulated at the state level.

Obtain written assurances from the carrier that the medical malpractice liability insurance policy covers telemedicine malpractice lawsuits.

Determine if the policy includes coverage for claims brought by a state board of medicine against the physician for standard of care and regulatory compliance issues.

Determine if the policy is occurrence-based or claims-made, so tail coverage (if desired) can be included in the decision process.

Verify the policy includes coverage for claims brought by a patient's estate.

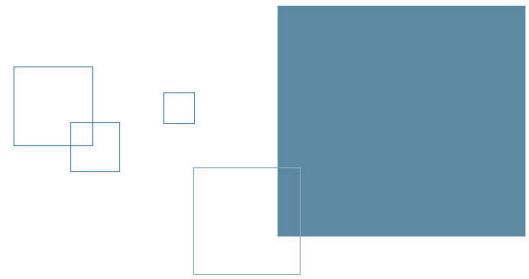
Explore the option of a separate service-line or add-on policy if the telemedicine service is only interpretive (e.g., telepathology, teleradiology) in a peer-to-peer consultation setting, and not a direct-to-patient model.

For More Information

Learn about how we can help you with telemedicine insurance coverage matters. Please contact your Foley attorney or the following:

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Managing Telemedicine Tort Liability

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Tort liability for telemedicine is rooted in negligence, and is generally a state-law issue.

The basis of tort liability rests on a breach of duty. In the medical context, the duty often arises when there is a doctor-patient relationship.

A direct-to-patient arrangement must first create a valid doctor-patient relationship as a predicate for the clinical services provided to the patient.

Take steps to clarify and document the scope of services and the scope of the doctor-patient relationship.

Consider including corresponding disclaimers and acknowledgements in the terms of use agreement signed by the patient when utilizing the telemedicine services.

A provider can take some additional steps to help reduce tort liability for telemedicine services, including the following:

- **Regularly poll patients** to assess their satisfaction levels with the telemedicine services, including the level of responsiveness and attention provided by the provider physicians. If a particular physician receives more than his or her share of complaints, it could be an indication of risk, as physicians who leave patients dissatisfied may be more frequent targets of claims.
- **Consider including, in the physician contracts, that the physician notify the provider** within five days of any complaints or requests for records from a patient or their legal representative.

- **Understand and follow the applicable laws and guidance** (including but not limited to licensing, scope of practice, remote prescribing and fraud & abuse) in states where the provider offers telemedicine services.
- **Provide direct-to-patient services** only in states where the physicians are licensed.
- **Understand and incorporate industry practice** guidelines and standards as appropriate.
- **Allow sufficient information, resources, etc.** for telemedicine consults to be provided in accordance with accepted standards of care and clinical practice.
- **Document patient understanding** of terms of use, limitations, and associated conditions.
- **Understand and follow the requirements and rules** for telemedicine informed consent in states where the provider offers services.

For More Information

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Does Delaware's New Telemedicine Law Foreshadow Broader Payment Parity?



BY NATHANIEL LACKTMAN

Nationwide, states continue to enact laws requiring commercial health plans to cover medical services provided via telemedicine to the same extent they cover medical services provided in-person. These laws are intended to promote innovation and care delivery in the private sector by catalyzing health care providers and plans to invest in and use the powerful telemedicine technologies available in the marketplace.

Delaware Telemedicine Commercial Insurance Requirements

Declaring “liberty and independence” from the constraints of brick and mortar health care, Delaware became the 29th state to enact a telemedicine commercial reimbursement statute. After unanimously passing both the House and Senate, the governor signed it into law on July 7, 2015, reflecting strong bipartisan support for telemedicine in Delaware. The new law takes effect immediately and positions Delaware to embrace efforts that will provide incentives for health insurers and health care providers to support the use of telemedicine and encourage state agencies to evaluate and amend

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their policies and rules to foster and promote the use of telemedicine services.

Delaware health plans now must cover services provided via telemedicine to the same extent the plan covers those services if provided through in-person visits. The law also protects patients against cost-shifting because health plans may not impose different deductibles, co-payments or benefit caps for services provided via telemedicine.

Payment parity levels the field. It does not eliminate or impair opportunities for cost savings, as plans and providers can voluntarily contract for alternative payment models.

The changes to Delaware's Insurance Code are more provider (and patient) friendly than some other states because Delaware requires not only coverage parity, but payment parity. Health plans must pay for telemedicine services on “the same basis and at least at the rate” the health plan pays for the “same service through in-person consultation or contact.” Moreover, the payment must include reasonable compensation for the transmission cost incurred during the delivery of telemedicine services.

The law also addresses health care services provided through “telehealth” (a broader definition into which telemedicine is subsumed), requiring health plans to cover telehealth “as directed through regulations promulgated by the [Insurance] Department.” The forthcoming regulations will be important, as they will define the shape and scope of specific coverage and payment rules for telehealth services in Delaware.

Whether a service is considered “telemedicine” or “telehealth,” Delaware's payment parity provision levels the field for hospitals and health care providers to enter into meaningful negotiations with health plans as to how these services are covered and paid. Payment parity recognizes that telemedicine technology is a conduit through which health care services are provided; not a different specialty itself. Payment parity does not eliminate or impair opportunities for cost savings, as plans and providers can voluntarily contract for alterna-

tive payment models. The new Delaware law does not prohibit health plans and providers from entering into at-risk, capitated, or shared savings methodologies, all of which are conducive to the benefits offered by telemedicine. These compensation models are real opportunities and should be meaningfully explored by plans and providers, alike.

The Power of Telemedicine in New Payment Models

Telemedicine technology is particularly suited to alternative payment methodologies because it allows the provider to better manage risk. Under a traditional fee-for-service (FFS) payment model, the payer (health plan) bears all the risk because the provider will get paid each time it performs a service. Under FFS, a provider has no incentive to manage the patient's health and the associated costs of care. Indeed, compensating a provider on a FFS basis incentivizes the provider to perform more services for more patients, as that is the only way for the provider to generate more revenue. This is compounded when health plans continue to seek "cost savings" by simply reducing the FFS payment rate.

Under a FFS model, payers manage risk through an extensive system of cost-shifting, audits, ever-increasing documentation rules, and complex coverage requirements. An entire industry has been born out of auditing, coding, and reimbursement appeals. These are real costs, as health plans and providers both maintain large claims auditing and appeals departments in a veritable arms race under the rubric of "utilization management."

The result: operating costs increase, margins narrow, doctors receive less compensation and take on greater patient volume, and patients are encouraged to "listen to their body" and become "patient self-advocates" navigating the health care system. A particular victim of the FFS model is chronic care management, and even CMS took steps this year to change this for the Medicare program.¹

¹ See <http://www.healthcarelawtoday.com/2015/07/15/can-my-hospital-bill-medicare-for-telehealth-chronic-care-management/>.

In contrast, under capitated, shared savings, or hybrid alternative payment models, the risk of loss is borne by the provider, who is responsible for managing the health of its patient population (hence the trending term "population health management). Utilization management, arcane coverage rules, and ubiquitous auditing is no longer the centerpiece because the provider, not the health plan, is financially responsible for the costs of care after being paid a capitated rate by the health plan. This is one reason for the vast differences in encounter data reported under capitated models vs. FFS models.

So, how does a provider manage this risk? The old-fashioned way: increased communication with patients, meaningful information exchange, periodic monitoring, and **developing the relationship** in the "doctor-patient relationship." Telemedicine is a powerful tool to accomplish this because it reduces barriers to accessing care, increases the convenience and likelihood a patient will visit the doctor, offers inexpensive remote patient monitoring tools to give the provider a stream of health information, draws on data mining, brings the doctor to the patient, and leverages specialist physician expertise. The increased patient 'touches' plus meaningful health information allows doctors to better assess and treat patient health on a long-term horizon. These are just a few ways telemedicine technology allows providers to manage risk far better than traditional brick and mortar practices. Telemedicine is the innovation of blending high-tech tools with "old-fashioned" doctor-patient relationships.

A number of Delaware hospitals and health care providers already offer telehealth services, and patients have been able to access virtual care as part of these health care delivery models. Surveys also indicate health care executives are optimistic on the benefits offered by telehealth.² The new law is expected to drive the Delaware commercial insurance market, allowing telehealth to be enjoyed by more patients across the State. Successes in Delaware will signal the promise of telemedicine coverage and payment parity as the remaining 21 states consider their own legislation.

² See <http://www.foley.com/2014-telemedicine-survey-executive-summary/>.