



# Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

JULY 2018



**Local expertise,  
regional teams,  
and multinational  
compliance**

---

an interview with  
**Jonathan Turner**

“ Our best teaching moments happen when our senior leaders reject questionable requests even before Compliance reviews or advises on it. ”

See page 17

## ARTICLES

### 48 **The criminal regulatory framework**

by **Greg Kelminson, JD** and **Jeffrey J. Ansley**

A look at government enforcement actions for Medicare fraud by corporations and individuals demonstrates the need for strong compliance programs.

### 56 **Insurance compliance risks facing telemedicine providers**

by **Morgan J. Tilleman**

Telemedicine providers can reduce or eliminate some risks by tailoring their product design, pricing structure, and contracts, based on state insurance laws and types of customer.

### 62 **[CEU] Privacy is dead. Ask Alexa!**

by **Luis Ospina**

Privacy officers will need a new set of skills to deal with perennial changes in technological advances and innovation.

### 65 **[CEU] Tracking business associate agreements: Where are yours?**

by **Jason Throckmorton**

Tips for keeping track of contracts and agreements, in case you are ever audited.

### 68 **Hiring veterans for compliance positions**

by **Casey S. Morey**

Military service can bring out the best traits and business skills in future compliance professionals, and veterans are well-suited for the job.

### 71 **Compliance 101: The OIG Work Plan: An essential tool for every healthcare compliance program**

by **Jasmine R. Foo**

By focusing on the source of healthcare oversight, your organization can stay ahead of issues that could otherwise lead to unpleasant surprise audits or reviews.

#### EDITORIAL BOARD

Gabriel Imperato, Esq., CHC, CT Contributing Editor  
Managing Partner, Broad and Cassel

Donna Abbondandolo, CHC, CHPC, CPHQ, RHIA, CCS, CPC  
Sr. Director, Compliance, Westchester Medical Center

Janice A. Anderson, JD, BSN, Shareholder, Polsinelli PC

Nancy J. Beckley, MS, MBA, CHC, President  
Nancy Beckley & Associates LLC

Robert Carpino, JD, CHC, CISA, Chief Compliance and Privacy  
Officer, Avanti Hospitals, LLC

Cornelia Dorfschmid, PhD, MSIS, PMP, CHC  
Executive Vice President, Strategic Management Services, LLC

Tom Ealey, Professor of Business Administration, Alma College

Adam H. Greene, JD, MPH, Partner, Davis Wright Tremaine LLP

Gary W. Herschman, Member of the Firm, Epstein Becker Green

David Hoffman, JD, FCPP, President  
David Hoffman & Associates, PC

Richard P. Kusserow, President & CEO, Strategic Management, LLC

Tricia Owsley, Compliance Director, University of Maryland  
Medical System

Erika Riethmiller, Director, Privacy Incident Program, Anthem, Inc

Daniel F. Shay, Esq., Attorney, Alice G. Gosfield & Associates, PC

James G. Sheehan, JD, Chief of the Charities Bureau  
New York Attorney General's Office

Debbie Troklus, CHC-F, CCEP-F, CHRC, CHPC, CCEP-I  
Managing Director, Ankura Consulting

**EXECUTIVE EDITORS:** Gerry Zack, CCEP, Incoming CEO, HCCA  
gerry.zack@corporatecompliance.org

Roy Snell, CHC, CCEP-F, CEO, HCCA  
roy.snell@corporatecompliance.org

**NEWS AND STORY EDITOR/ADVERTISING:** Margaret R. Dragon  
781.593.4924, margaret.dragon@corporatecompliance.org

**COPY EDITOR:** Patricia Mees, CHC, CCEP, 888.580.8373  
patricia.mees@corporatecompliance.org

**DESIGN & LAYOUT:** Pete Swanson, 888.580.8373  
pete.swanson@corporatecompliance.org

**PROOFREADER:** Bill Anholzer, 888.580.8373  
bill.anholzer@corporatecompliance.org

**PHOTOS ON FRONT COVER & PAGE 16:** Karen E. Segrave |  
KES Photo

**Compliance Today (CT)** (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Subscription rate is \$295 a year for nonmembers. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to Compliance Today, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Copyright © 2018 Health Care Compliance Association. All rights reserved. Printed in the USA. Except where specifically encouraged, no part of this publication may be reproduced, in any form or by any means without prior written consent of HCCA. For Advertising rates, call Margaret Dragon at 781.593.4924. Send press releases to M. Dragon, 41 Valley Rd, Nahant, MA 01908. Opinions expressed are not those of this publication or HCCA. Mention of products and services does not constitute endorsement. Neither HCCA nor CT is engaged in rendering legal or other professional services. If such assistance is needed, readers should consult professional counsel or other professional advisors for specific legal or ethical questions.

VOLUME 20, ISSUE 7

by Morgan J. Tilleman

# Insurance compliance risks facing telemedicine providers

- » Surprisingly, telemedicine contracts often create insurance compliance risks.
- » Unlimited or subscription programs for consumers are a high risk.
- » Capitated arrangements with self-funded plans are also high risk.
- » Direct primary care laws cover telemedicine-based primary care.
- » Telemedicine providers can mitigate risk with thoughtful contract structures.

*Morgan J. Tilleman (mtilleman@foley.com) is Senior Counsel at Foley & Lardner LLP in Milwaukee, WI.*

**T**elemedicine providers can sell their services in a number of ways. Consumers, self-funded health plans, and health insurance companies are all important and growing customers for many telemedicine providers.

Telemedicine providers have taken a wide range of approaches to contracting with these customers. Many of these approaches have included pricing that is *not* fee-for-service, and can create risks under state insurance law. Although the number of pricing models is nearly infinite, it is useful to think about three

- models for pricing telemedicine services:
1. Unlimited—users pay a fixed amount and receive unlimited access to telemedicine services.
  2. Hybrid—users pay a fixed amount and receive a fixed, limited amount of telemedicine services. These models may also include access to services beyond the fixed amount at additional cost.

3. Fee-For-Service—users pay a fixed amount for each consultation, potentially with discounts for greater volume.

Offering telemedicine services through these three approaches involves varying amounts of risk, which varies both by approach and by customer (i.e., selling to consumers comes with greater risk than selling to health insurers). This article identifies the insurance law risks faced by telemedicine providers and also identifies how those providers can reduce or eliminate their risk by tailoring their product design based on the state and type of customer.

## Insurance law risks

The most significant insurance law risk facing telemedicine providers is that those providers will be deemed a health insurance company under state insurance law, because they offer consumers telemedicine services on the unlimited model or possibly the hybrid model if it contains significant discounts below the market price for similar services. If a telemedicine provider is deemed to be an insurer, it could be subject to monetary penalties, cease-and-desist orders, and other regulatory action



Tilleman

from state insurance commissioners where the provider delivers its services. Generally, state law only permits licensed insurers to engage in the “business of insurance.” A number of insurance risks are relevant to the question of whether an entity has engaged in the business of insurance under state law, but for telemedicine providers, the most important type of risk is “utilization risk”—the risk that consumers will use more telemedicine services than they pay for. This risk is the primary risk covered through health insurance.

### Case law

This risk is illustrated by two cases, one in Illinois and another in Florida. In Illinois, insurance was first defined more than 120 years ago as “an agreement by which the insurer, for a consideration, agrees to indemnify the insured against loss [or] damage.”<sup>1</sup> Much more recently, an Illinois appeals court applied this definition to a pre-paid home healthcare services contract. That court found that a pre-paid home health contract with no incremental cost for increasing utilization constituted insurance.<sup>2</sup> Pre-paid home health is very similar to pre-paid telemedicine services, and any provider adopting the unlimited model for use with consumers in Illinois is at significant risk of such a product being deemed insurance by the Illinois regulator as well.

In Florida, a similar home health care product was also deemed insurance by a state appeals court.<sup>3</sup> There, Liberty Care Plan sold a membership that entitled members to purchase home healthcare services at a discount of approximately 50% from the market price for such services in Florida at the time. The court found that this membership was insurance; it wrote, “The Plan is a contract whereby [Liberty] undertakes to allow a determinable benefit (i.e., home health care services at discount rates) upon a determinable contingency

(i.e., the member’s exercise of the option to purchase these home health care services at discount rates).” Like the law in Illinois, this case suggests that providing unlimited access to care, or even just below-market discounts for a fixed cost, would place a telemedicine provider at risk of being deemed an insurer.

Not all risk transfer is sufficient to render an agreement “insurance” under state laws, however; nearly all contracts contain some element of risk transfer, whether through indemnification or otherwise. One illustrative case, where contracts were found not to be insurance even though they contained some risk transfer, is the case of collision damage waivers in car rental agreements. A California court held that the availability of collision damage waivers in car rental agreements did not constitute insurance, because the collision damage waiver was incidental to a contract whose main purpose was car rental, not insurance.<sup>4</sup> Following this logic, a contract for telemedicine services might contain a risk transfer element (e.g., through the provision of discounts or the offering of a specified number of consultations for a fixed fee) without becoming “insurance” under state law, as long as the risk transfer is incidental to a contract for healthcare services rather than the primary objective of the contract. There is relatively little case law guidance on this point, however, so telemedicine providers must determine whether they are comfortable with any particular method of pricing telemedicine services in the context of insurance law compliance risk.

### Direct primary care laws

Fortunately for telemedicine providers, a number of state legislatures have adopted so-called “direct primary care” laws that permit healthcare providers to sell pre-paid primary care services without fear of insurance regulation. These laws were originally

adopted to permit doctors to open concierge and similar types of practices and charge patients a flat fee for primary care. Although telemedicine providers weren't the focus of these laws, they are generally applicable to telemedicine providers who deliver primary care. Today, fewer than half of states have a direct primary care law on the books, so the opportunities are real for telemedicine providers in the primary care space, but not universal.

Florida very recently adopted a direct primary care law that explicitly carves direct primary care practices out from the Florida Insurance Code.<sup>5</sup> This law, which will permit telemedicine providers to offer primary care services on the unlimited

model, takes effect in July 2018 and applies to primary care providers who enter into "direct primary care agreements" with individuals and families. A primary care provider is defined as a licensed healthcare provider, however. This means that, in order to

take advantage of Florida's direct primary care law, telemedicine providers must establish contracts directly between consumers and providers (likely through a professional corporation)—contracts with a service company do not qualify for the insurance law exemption provided by Florida's new law.

A number of other significant jurisdictions, including Michigan, Texas, and Washington also have direct primary care laws.<sup>6</sup> Under Michigan and Washington law, both primary care providers and their agents (e.g., a management company) can enter into direct primary care contracts; this makes it easier for a typical telemedicine provider to enter into such contracts. However, under some direct

primary care laws, including those in Texas and Washington, the provider is prohibited from billing a patient's insurance company for services provided under a direct primary care agreement.

### **Contracting with self-funded plans**

Many telemedicine providers have sought to contract with self-funded employee health and welfare plans; telemedicine is a great ancillary benefit for employers seeking to develop attractive benefit plans that manage or reduce total healthcare costs, because it can reduce emergency room and other high-cost encounters.<sup>7</sup> Generally, if a telemedicine provider contracts with self-funded plans on

a fee-for-service model, there is no insurance regulatory risk associated with that contract. If, however, the telemedicine provider contracts on a capitated basis (such as a "per member, per month" contract or a flat fee for unlimited access for covered employees and their dependents),

there could be significant insurance risk associated with that contract.

State insurance regulators have typically taken the position that only licensed insurance or HMO entities can take downstream risk from a self-funded health plan, including through capitation arrangements. This is reflected in the National Association of Insurance Commissioners' published guidance for state regulators relating to ERISA self-funded plans.<sup>8</sup> Section VIIJ of that guidance takes a strong position; to the extent that an entity "assumes insurance risk through the receipt of a prepayment from a purchaser for the delivery or the arrangement of the delivery of health care benefit services, it is subject to

...telemedicine is a great ancillary benefit for employers seeking to develop attractive benefit plans that manage or reduce total healthcare costs...

state insurance laws.”<sup>9</sup> This statement would apply to a telemedicine provider today, even though it was originally intended to address physician-hospital organizations and other managed care organizations. If a telemedicine provider receives prepayment and insurance risk (including utilization risk, as discussed above) it could be subject to insurance regulation.

This guidance is consistent with bulletins issued by a number of insurance regulators in the mid-1990s, most of which still remain in effect. For instance, an Oregon Insurance Division bulletin, which is similar to many others issued by state regulators at the time, made clear:

An agreement between one or more health care providers and one or more purchasers of health care services constitutes the transaction of insurance if ...the purchaser(s) are individuals or entities that have not been issued a certificate of authority and are not specified in the Insurance Code as exempt...and [t]he provider(s) are compensated for the actual or potential delivery of health care services in a manner that involves risk sharing such as capitation, a fixed or “global” payment, or any similar arrangement.<sup>10</sup>

Any contract for telemedicine services on a capitated, per-member per-month or similar basis thus creates risk that a state insurance regulator will view the contract as unlicensed insurance.

### **Contracting with health insurers**

Unlike telemedicine contracts with consumers and self-funded benefit plans, which must be carefully structured to avoid state insurance law risks, telemedicine contracts with licensed insurers and HMOs can be structured and priced on any model that the insurer and

telemedicine provider agree upon, without incurring meaningful insurance risk. In this context, capitation and other methods of risk transfer to providers are widely used by insurers and universally accepted by state insurance regulators because of the insurer/HMO’s state license. Essentially, the regulator wants one licensed entity in the chain of financial responsibility. The Maryland insurance regulator puts it this way: “[B]ecause the carrier [that enters into capitation arrangements] remains responsible for the fulfillment of the insurance contract or HMO contract, health care providers paid capitation are not required to obtain a certificate of authority.”<sup>11</sup> This general approach, followed in most states and most circumstances, allows telemedicine providers to structure risk contracts with health insurers and HMOs with minimal worry of violating state insurance laws.

### **How to structure your telemedicine offerings**

In light of the insurance law compliance risks discussed above, telemedicine providers should always think about whether a particular contract contains insurance risk or not. Contracts on a fee-for-service basis and contracts with health insurers or HMOs do not generally contain meaningful insurance compliance risk, so the telemedicine provider can choose to offer pre-paid or capitated services or fee-for-service contracts. For contracts with individual consumers or self-funded health plans that are not on a strict fee-for-service basis, telemedicine providers must consider how to mitigate insurance compliance risk. Reducing the risk transfer associated with such contracts to an incidental feature is one method for risk mitigation that works on contracts with individuals and self-funded plans, and in all states. Providers should consider limiting the number of consultations available to any single person to a reasonable amount where the provider would break even or make

money, even if most covered persons used most of the consultations available to them. In some states, where direct primary care laws have been adopted, telemedicine providers delivering primary care (and not specialty care, such as psychiatry) may be able to offer subscription-based contracts to individual consumers and families, subject to the exact terms of the applicable direct primary care laws. These laws do not apply to contracts with self-funded plans, however.

In short:

- ▶ Contracts with health insurers and HMOs can be capitated, and do not create meaningful insurance law compliance risks.
- ▶ Contracts with self-funded plans must not transfer significant utilization risk to the telemedicine provider. Providers should seek fee-for-service pricing structures with self-funded plans, but can include volume discounts if appropriately sized.
- ▶ Contracts with individuals should not include significant utilization risk, unless

they are specifically structured to comply with the direct primary care laws of a particular state.

These guidelines provide telemedicine providers with a roadmap for better compliance with state insurance laws and a method for mitigating the risk of an unwanted and unwelcome letter or visit from a state insurance regulator. ☺

1. See *Barnes v. People ex rel. Moloney*, 48 N.E. 91 (Ill. 1897) (addressing property insurance).
2. *Homeward Bound Servs. v. Ill. Dep't of Ins.*, 365 Ill. App. 3d 267 (Ill. App. 2006).
3. *Liberty Care Plan v. Dep't of Ins.*, 710 So.2d 202 (Fla App. 1998).
4. *Truta v. Avis Rent A Car System, Inc.*, 193 Cal. App. 3d 802 (Cal. App. Ct. 1987).
5. Chapter 2018-89 of the Florida Laws (creating Section 624.27, Fla. Stat.).
6. Mich. Comp. Stat. § 500.129; Tex. Occupations Code § 162.251 et seq., Va.
7. Jessica Kim Cohen: "Study: Telehealth program reduces unnecessary ED visits by 6.7%" *Becker's Hospital Review*; February 27, 2017. Available at <http://bit.ly/2KPLI0P>.
8. National Association of Insurance Commissioners: Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation. 2004. Available at <http://bit.ly/2scdzjV>.
9. Id. at 57.
10. See, e.g., Oregon Insurance Division Bulletin INS 96-2. April 1996. Available at <http://bit.ly/2xeK5aU>
11. Maryland Insurance Administration Bulletin 08-19. September 5, 2008. Available at <http://bit.ly/2KUkSVm>.

# Research Compliance Professional's Handbook

## Second Edition

Get HCCA's practical guide to building and maintaining a clinical research compliance & ethics program

### Covers:

- human subject protections
- biosecurity and biosafety
- research using animals
- scientific misconduct
- conflicts of interest
- grant and trial accounting
- effort reporting
- privacy and security (includes Omnibus Rule)
- clinical trial billing
- records management
- data and safety monitoring
- role of oversight entities
- auditing & monitoring
- integrating research compliance into corporate compliance



Published by Health Care Compliance Association (HCCA) Copyright © 2018 HCCA. All rights reserved.

[hcca-info.org](http://hcca-info.org) | 888.580.8373